SAINT FRANCIS
Hospital and Medical Center

Steven H. Rosenberg
Senior Vice President and
Chief Financial Officer

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101

June 1, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1488-P; Medicare Program; Proposed Changes to Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates

Dear Sir or Madam:

Saint Francis Hospital and Medical Center welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006). The CMS proposed rule sets forth numerous operational and policy changes to the hospital inpatient prospective payment system (IPPS). The comments provided herein explain our concern over a number of the proposed operational and policy changes and the detrimental impact on Saint Francis Hospital and Medical Center.

A. Comment Summary

- Saint Francis Hospital and Medical Center opposes the proposed (HSRVcc) hospital-specific relative value cost center weighting methodology to adjust DRG relative weights.

- Saint Francis Hospital and Medical Center strongly urges the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

B. Comment Detail

Hospital-specific weighting methodology for DRG relative weights (HSRVcc)

CMS is proposing to use hospital-specific relative values for 10 cost centers to compute DRG relative weights. Saint Francis Hospital and Medical Center does not support this change and requests that CMS further review the HSRV methodology being used to develop DRG relative weights.

The standard lines on the Medicare cost report for ancillary services are limited and hospitals and/or intermediaries have created subscripted lines for ancillary services in order to ensure proper cost finding. The hospital is concerned that the HSRV methodology relies on CMS mapping definition of hospital charges (UB 92 revenue codes) to hospital cost center costs. The HSRV methodology assumes that the charges from UB-92 revenue code 480 (Cardiology) are mapped on the cost report to line 53 (EKG) or line 54 (EEG), but for our hospital the costs for Cardiology have been included on subscripted line 59.01. The same situation occurs for Radiology, where CT Scan (revenue code 350) and MRI (revenue code 610) are assumed by CMS to be mapped to Radiology, but the costs for these services are on subscripted lines 59.02 CT Scan and 59.03 MRI.

Given the magnitude of this proposed change and the concern that we have stated above, we believe that the proposed DRG relative weights under HSRV methodology should not be implemented for FY 2007.

Resident Time in Patient-Related Activities

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. The activities cited in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Steven H. Rosenberg
Senior Vice President and Chief Financial Officer

102

Clarion Hospital

June 6, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1488–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS–1488–P
April 25, 2006, IPPS Proposed Rule
Submission of Comments

Dear Sir or Madam:

We appreciate this opportunity to comment on the inpatient PPS fiscal 2007 proposed rule published in the April 25, 2006, **Federal Register**. We are a rural hospital located in Clarion, Pennsylvania. Our provider number is 39-0093. Our comments are as follows:

Hospital Redesignations and Reclassifications

CMS publishes a list of hospitals qualifying for geographic reclassification for fiscal year 2007 in Table 9A. Several Pennsylvania hospitals appear to have inadvertently been left off this list and incorrectly included as on table 9C as rural Pennsylvania hospitals reclassified to rural Pennsylvania.

We received a reclassification for wage index only to the Pittsburgh, PA MSA for the Federal fiscal years 2005 to 2007 from MGCRB case no. 05C 0231. In the August 12, 2005 Federal Register, we were correctly listed with the wage index as a hospital reclassified to the Pittsburgh, PA CBSA (38300). We should have one more year left on our three-year reclassification.

We have been incorrectly included in Table 9C as a hospital that has elected to be treated as a rural hospital under Section 1886(D)(8)(E) of the Act. Table 9C shows us as being redesignated from rural Pennsylvania to rural Pennsylvania, which is obviously in error. Please delete our hospital from table 9C and include us on table 9A as a rural Pennsylvania hospital reclassified to the Pittsburgh, PA CBSA for wage index.

Sincerely,

Vincent Lamorella

Vincent Lamorella
Chief Financial Officer

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103

Avera St. Luke's

Sponsored by the Benedictine and Presentation Sisters

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Aberdeen, SD 57401
(605) 622-5000

www.averastlukes.org

June 9, 2006

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Systems and Fiscal Year 2007 Rates; Fed. Reg. 23,996 et seq. (Apr. 25, 2006); CMS-1488-P

Dear Sir or Madam:

The purpose of this letter is to provide comments related to the above proposed changes. My comments will focus on those related to **SCH/MDH Changes in Qualification Status**.

Avera St. Luke's (ASL) is a Sole Community Hospital and a Rural Referral Center located in Northeastern South Dakota. We serve a primary and secondary service area of 100,000 plus. Our facility provides comprehensive acute health care services to this area and is the largest hospital within a 180 mile radius. We have many specialties that would be found in larger urban areas and tertiary hospitals.

From a demographic standpoint, we are surrounded by many Critical Access Hospitals (CAH) and have one specialty hospital located in Aberdeen. With respect to the CAH facilities, the closest facilities would be 40 miles to the south, 50 miles to the east, 60 miles west and 70-80 miles to the northwest. As you are aware, most CAH lack full-time emergency room services, obstetrics, intensive care, surgical services, and various technological services. The closest acute care hospitals (non-specialty hospitals) are 100 miles from Aberdeen.

As the above paragraph describes, there is no like acute hospital within miles of our facility except the specialty hospital that falls into the category of acute since it is a licensed hospital. We are truly a SCH that provides the single access for many services due to our geographic isolation and give the other CAH facilities the healthcare infrastructure that is critical to their communities.

Our concerns with the proposed regulations and reporting requirement and penalties are problematic for a number of reasons. These need to be clarified and revised to be consistent with the intended purpose of the SCH program.

We suggest the following:

CMS and its fiscal intermediaries should maintain hospital status, patient admissions and patient day data and periodically evaluate this data for SCH eligibility due to:

- Hospitals, even though they are aware of the market place, are not in the best position to monitor compliance. They may not know if a CAH converts back to an acute facility.
- Obtaining the information necessary to calculate the various numeric values to qualify is sometimes hard to obtain by a hospital and requires many facilities to obtain this data from the intermediary through the Freedom of Information Act. This means cost reports are not available until at least five months after a year end. This also means there is no way to prospectively calculate certain data and everything is on a retrospective basis.
- For those that use the 8 percent threshold to identify "Like Hospitals" the data is simply not available on a timely basis.
- It is not reasonable for a hospital to monitor and know all the other factors associated with SCH designation at a given time. These include road closures, weather conditions, etc.

CMS needs to expand the 30 day timetable for canceling SCH status when a hospital self-reports. We would suggest at least 12 months.

Retroactive penalties should only apply when a hospital had actual knowledge that it no longer qualified for the reasons noted above plus a hospital's inability to know everything it its region that relates to how it qualifies or does not qualify.

CMS should re-evaluate the definition of "Like Hospital" due to:

- The current 8 percent threshold was arbitrarily decided and not based on any empirical study or evidence.
- Specialty hospitals are a threat to SCHs due to siphoning off patients with payer mixes that produce very high margins (30-50%), increasing expenses at the SCH since there are fewer patients to cover the overhead of a full service hospital.
- Specialty hospitals in many cases do not provide a community the full scope of services. They will minimize costs by not including a full-time lab, full-time radiology, 24 hours in-house physician coverage in the ER, obstetrical services, medical services, respiratory therapy, complete array of technology, community services, etc.
- Their ability to provide emergency care to their inpatients is very limited and procedures involve calling the ambulance or 911 in the case of an emergency to transfer the patient to a "True" acute hospital.

- Patient days in an acute facility continue to decrease due to technology and outpatient services. Patient days at a specialty hospital may increase due to talking more patients out of the market that do not require a high level of care or that are more profitable in the for-profit setting. In the end, with the 8 percent test, it becomes much harder to meet since the 8 percent is over a lesser number for the acute hospital. This again shows how problematic the 8 percent is given no concrete data or analysis was used to determine what should be used.
- In a rural market such as ours, the population is not growing but rather decreasing. This results in fewer inpatients, therefore, less days. While a specialty hospital is seeing a small subset of the population, they continue to see the same patient days or they bring additional procedures with high profitability at the expense of the acute hospital, increase their days and the full service acute hospital then sees the patient day margin (8%) becoming an issue.
- MEDPAC and CMS have both realized there is a disparity on how an acute hospital is paid compared to a specialty hospital and have proposed changes in DRGs to somewhat compensate for this. We support this change and would add that by making this change, CMS is agreeing that specialty hospitals are different than acute hospitals. This alone should result in CMS examining the definition of a "Like Hospital."
- Some specialty hospitals consider themselves as a "Surgical Center" since it is used in their name. This can easily be interpreted to mean they consider themselves not to be an acute hospital.

Please call me at 605-622-5272 if you have any questions about these comments.

Sincerely,

Geoff Durst
Vice President of Finance.

104

Temple University Physicians

Department of Orthopaedic Surgery

JOSEPH J. THODER, JR., M.D.
Chairperson
The John W. Lachman Professor
Hand and Upper Extremity Surgery
General Orthopaedic Surgery
Trauma

PHILIP D. ALBURGER, M.D.
Pediatric Orthopaedic Surgery
Sports Medicine

E. BALASUBRAMANIAN, M.D.
Joint Reconstruction
General Orthopaedic Surgery

WILLIAM G. DELONG, JR., M.D.
Trauma
Sports Medicine
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KRISTINE L.Z. FORTUNA, M.D.
Pediatric Orthopaedic Surgery
General Orthopaedic Surgery

JOHN D. KELLY, IV, M.D.
Sports Medicine
Shoulder
General Orthopaedic Surgery

STANLEY P. MICHAEL, M.D.
Joint Reconstruction
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PEKKA A. MOOAR, M.D.
Joint Reconstruction
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RAY A. MOYER, M.D.
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General Orthopaedic Surgery

SAQIB REHMAN, M.D.
Trauma
General Orthopaedic Surgery

EDWARD J. RESNICK, M.D.
General Orthopaedics

GENE W. SHAFFER, M.D.
Foot and Ankle Reconstruction
General Orthopaedic Surgery

JOSEPH S. TORG, M.D.
Sports Medicine
General Orthopaedics

BRUCE B. VANETT, M.D.
General Orthopaedic Surgery

ALBERT A. WEISS, M.D.
Hand and Upper Extremity
General Orthopaedics

F. TODD WETZEL, M.D.
Spine Surgery

May 31, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X STOP
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir/Madam:

In my orthopedic practice, I see a significant number of patients who present with debilitating LSS. The X Stop should be viewed as a good treatment option for LSS patients who do not wish to consider conventional surgery or are not medically able to do so.

Most of the LSS patients in my practice receive epidural steroids and physical therapy for 6 to 8 weeks. Rarely do I prescribe NSAIDS, but I do prescribe gabapentin and analgesics. All steroid injections are done by the pain management clinic. Among my caseload, only 10 percent of patients are referred to laminectomy; 90 percent would not be candidates for surgery. In the past year, I have begun offering the option of X Stop to non-surgical candidates. It is less invasive than surgery and very safe.

All of the X Stop procedures are performed in the hospital inpatient department, with the vast majority under general anesthesia. I have found that my X Stop patients experience significantly improved mobility and decreased analgesic usage.

In my opinion, the X Stop should be considered a viable treatment to expand our treatment armamentarium.

Sincerely,

F. Todd Wetzel, M.D.

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105

University of California
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School of Medicine
Departments of Neurology & Neurological Surgery

Center for the Surgical Treatment of Movement Disorders

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June 8, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-1488-P
DRGs: Neurostimulators

To Whom it May Concern:

We write concerning the impending expiration of the New Tech Add-On Payment for the Kinetra deep brain stimulation neurostimulator.

We are one of the nation's most experienced centers in providing deep brain stimulation therapy to patients with Parkinson's disease and other neurological disorders. With the expiration of the New Tech Add-On Payment, we are concerned that full-system Kinetra implants will be inadequately reimbursed in their current DRGs (001 and 002). We encourage CMS to move full-system Kinetra cases into DRG 543 in fiscal year 2007, given the similarity in resource consumption.

Unless the therapy is moved into a clinically coherent DRG that adequately reflects the costs associated with a full-system Kinetra implant, financial barriers will impact our ability to provide this important and medically necessary therapy to Medicare patients who suffer from Parkinson's disease.

We urge thoughtful consideration of this matter.

Sincerely,

William J. Marks, Jr., M.D.
Associate Professor of Neurology
Medical Director

Jill L. Ostrem, M.D.
Assistant Professor of Neurology

Philip A. Starr, M.D., Ph.D.
Associate Professor of Neurological Surgery
Surgical Director

Paul S. Larson, M.D.
Assistant Professor of Neurological Surgery

CHRISTUS®
SANTA ROSA
Children's Hospital

June 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05 – Express Mail Delivery
500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Hospital IPPS Rule
Hospital-within-a-Hospital Provisions

Dear Secretary Leavitt:

CHRISTUS Santa Rosa Children's Hospital in San Antonio, TX, appreciates the opportunity to submit comments that address the Centers for Medicare and Medicaid Services (CMS) proposal to modify the "grandfathering" provisions of the "hospital-within-a-hospital" rule appearing at 42 C.F.R. § 412.22(f). As CMS states in the preamble, it "has been urged to modify [its] policies to allow these grandfathered entities to increase in square footage and number of beds without requiring compliance with the "separateness and control policies."

In particular, CHRISTUS Santa Rosa Children's Hospital is a grandfathered children's hospital within a hospital, and it endorses the comments submitted separately by National Association of Children's Hospitals (N.A.C.H.), N.A.C.H. recommends exclusion of grandfathered children's hospitals-within-hospitals from the prohibition on change in bed size or square footage, which took effect October 1, 2003. As N.A.C.H. explains, this rule seriously, adversely affects three children's hospitals' ability to serve all children, including our own, despite the fact that the continued application of the rule serves no Medicare policy or financial interest and there is substantial precedent for different treatment of children's hospitals under Medicare inpatient prospective payment system (IPPS) policy.

In particular, I call to your attention the very substantial need in our community for CHRISTUS Santa Rosa Children's Hospital to be able to expand our pediatric services. Both alternatives of compliance with the prohibition on change in beds/square footage or loss of our status as a Medicare IPPS excluded children's hospital would jeopardize our ability, as a major safety net institution that also makes a major contribution to our region's pediatric workforce, to meet the needs of all children.

CHRISTUS Santa Rosa Children's Hospital serves more than 90 counties in South Texas. South Texas and all of Texas are experiencing an explosion in the child growth rate. Texas has the fastest growing child population in the U.S. South Texas will increase in child population

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Tel 210.704.2011

by 200,000 in the next five years. CHRISTUS Santa Rosa Children's Hospital has a strong academic affiliation with the University of Texas Health Science Center at San Antonio and is a partner with the military's Wilford Hall-Brooke Army pediatric training program. As our patient population and our residency training programs grow we need the capability to add new service lines and implement new technology. These rules do not provide us the needed flexibility to meet our community's needs and current state of the art care standard.

In conclusion, CHRISTUS Santa Rosa Children's Hospital supports the recommendation of N.A.C.H. and urges you to extend the precedent of exemption of children's hospitals under the agency's growth prohibition on satellite facilities to growth prohibition on grandfathered hospitals-within-hospitals.

Sincerely,

Richard S. Wayne, M.D.

Richard S. Wayne, M.D.
Executive Regional Vice-President and Administrator

107-0

Sisters of Charity of St. Augustine Health System

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June 12, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services (CMS)
REF: CMS-1488-P and P2
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year 2007 Payment Rates; Proposed Rule.

Dear Dr. McClellan:

I write on behalf of the Sisters of Charity of St. Augustine Health System (CSA Health System), serving the communities of Canton and Cleveland, Ohio, and Columbia, South Carolina. We are the parent organization for five hospitals, three foundations, and several health and social service organizations and programs.

In the main, the CSA Health System is exceptionally concerned about the long-term impacts of these proposed changes and believes they may ultimately be very negative for us and the larger hospital industry.

We wish to echo the concerns expressed by the Catholic Health Association and the American Hospital Association regarding the proposed regulatory changes to the Medicare hospital inpatient prospective payment system. The proposed rule's methodology dramatically affects larger, non-profit community hospitals, including teaching hospitals and those committed to innovation and research. Based upon the proposed IPPS changes, we anticipate we will experience a system-wide negative impact of approximately $7.5 million in lower revenue. In particular, because of the significant affects to cardiology, our Sisters of Charity Providence Hospitals in Columbia, South Carolina, may see revenue losses between $7.1 to $8.4 million (severity changes where not included in these calculations).

Supporting the Catholic Health Association and American Hospital Association's comments, firstly, we recommend that CMS postpone until at least FY 2008 implementation of the proposed hospital specific cost-based diagnostic related groups (DRG) relative weight

determination policy. Further analysis of unintended consequences should be determined during this extended timeframe.

Secondly, we also support the comments that encourage proposed hospital specific cost-based DRG relative weight determination policy and the proposed severity adjustment policy be implemented simultaneously, but no earlier than FY 2008 if it is determined that the DRG changes should move forward. As our Catholic health care trade association noted, "This simultaneous implementation approach should help to insure that redistribution of hospital payments is not unduly disruptive to selected individual hospitals." One of our hospitals within the CSA Health System noted that the impact of these changes might be lessened if the DRG severity changes were implemented at the same time rather than a year later. For instance, both large and small hospitals will be reimbursed more for a pneumonia case, but the hospitals performing more surgery and cardiac care will have offsetting *reductions* while the smaller hospital will not. If the severity changes were implemented at the same time, the larger hospital – often treating more complex and serious cases – would receive a higher severity payment helping to mitigate the reductions felt by the weighting changes proposed.

Thirdly, we agree that CMS should provide for at least a three-year transition period during which hospitals are protected from major payment disruptions and redistributions.

Because of the negative impacts to community hospitals, lastly, we urge CMS to maintain a moratorium on new specialty hospitals during this timeframe.

Following the 154-year tradition of the Sisters of Charity of St. Augustine, we work to further the Lord's healing ministry, in particular for those individuals in our communities who are medically indigent. Thank you for the opportunity to comment on the proposed rule. Bless you and thank you for your public service.

Sincerely,

Sr Judith Ann Karam, CSA

Sr. Judith Ann Karam, CSA
President & CEO
Sisters of Charity of St. Augustine
Health System

cc: Northeast Ohio and South Carolina Congressional Delegations

June 9, 2006

VIA Overnight Mail
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

This letter is written on behalf of the Alabama Hospital Association's (AlaHA) 120 member hospitals, health care systems and other health care organizations. We appreciate this opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rule.

The rule proposes the most significant changes in the diagnosis-related group (DRG) relative weights since 1983. The proposed rule would create a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology. It would also refine DRGs to account for patient severity, with implementation in FY 2008. The proposed rule would update payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for rural hospitals and medical education, among other policies.

While our association supports some of the proposed rule's provisions, we also have serious doubts about the proposed changes to the DRG weights and classifications.

Hospitals support meaningful improvements to Medicare's inpatient PPS. There is a common goal to refine the system to create an equal opportunity for return across DRGs, which will provide an equal incentive to hospitals across the nation to treat all types of patients with various conditions. More time is needed to understand the significant proposed policy changes, which would redistribute from $1.4 to $1.7 billion within the inpatient system. The impact of the proposed changes is highly unstable, with small changes in methodology leading to big changes

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in hospital payment. The validity of CMS' proposals to improve the DRG weights and classification system is very uncertain.

Specifically, AlaHA supports the following:

1. AlaHA commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

2. AlaHA believes a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology is appropriate. AlaHA is committed to working with CMS to address these concerns.

3. Any changes should be implemented with a three-year transition period, because of the magnitude of payment redistribution across DRGs and hospitals. Alabama could wind up a significant net loser.

4. If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the two generally off-setting changes.

5. AlaHA does not support a new classification system at this time, as the need for a new system is still unclear. Much more work in understanding the variation within DRGs and the best classification system to address that variation is still needed before another system should be selected or advanced.

6. AlaHA supports moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed method appears intrinsically flawed. This movement from the current system to the proposed system will reduce payments to Alabama hospitals by 1.9% or $35 million per year.

7. Sixty of 98 acute care hospitals will lose 3.9% of their Medicare reimbursement, or about $47.5 million a year. Only 38 acute care hospitals will gain (2.1%) on their Medicare reimbursement, or about $12.5 million a year.

8. CMS should use estimated CAH data in the FFY 2007 wage index file to compute the National Average Hourly Wage. Otherwise, the Medicare payment to all IPPS hospitals nationwide will be understated by approximately a half billion dollars.

9. CMS should make the quality data collection prospective. This could be accomplished by requiring that hospitals that want a full market basket update pledge to submit the relevant data for all 21 measures for patients beginning on or after July 1.

We further support the analysis submitted by the American Hospital Association and ask that CMS carefully consider the AHA's comments regarding the proposed rule.

AlaHA appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact Tom Cooper or me at (334) 272-8781.

Sincerely,

J. Michael Horsley
President / CEO

109

NCHA
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North Carolina Hospital Association

June 9, 2006

Mark McClellan, M.D. Ph. D.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S. W.
Washington, DC 20201

Reference: CMS-1488-P Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

The North Carolina Hospital Association (NCHA) represents more than 100 acute care hospitals in the State of North Carolina. NCHA welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed inpatient payment rules displayed on April 12, 2006.

DRG Reclassifications & Cost-Based Weights

The recommendations of CMS in both the FY 2007 and FY 2008 DRG payment process continue to ignore a large opening created by CMS to obtain and process claims without the complete medical history of the patient. CMS continues to allow the Fiscal Intermediaries to use software built prior to the implementation of HIPAA 837i transactions. Currently, Fiscal Intermediaries strip data from the electronic claim in the diagnosis and procedure areas to allow only the limited fields which are available on the paper UB-92. CMS should to require all Fiscal Intermediaries to make changes which would include acceptance of all the ICD9 diagnosis and procedure codes reported by providers in the development of any DRG reimbursement. The existing limitations in the CMS grouper alters the true patient severity for both provider reimbursement and quality data.

Transparency of Health Care Information

The proposed rule includes the introduction of a proposed initiative to expand the public availability of consumer information on health care quality and pricing.

While progress has been made regarding quality transparency, similar information on hospital pricing is less accessible. In the proposed rule, CMS details four options for providing pricing information to health care consumers, including:

- Publishing a list of hospital charges, either for every region of the country or selected regions of the country;

- Publishing the rates that Medicare actually pays to a particular hospital for every DRG, or for selected DRGs, which could be adjusted to account for the hospital's labor market area, teaching hospital status and DSH status;

- Establishing conditions of participation for hospitals that relate to the posting of prices and/or the posting of their policies regarding discounts or other assistance for uninsured patients; and

- Posting total Medicare payments for an episode of care. Under this proposal, CMS could include the costs for an inpatient hospital stay, physician payments (including the surgeon and the anesthesiologist), and payments for post-acute care services such as those provided in an inpatient rehabilitation facility, skilled nursing facility or long term care hospital for a certain service (such as hip replacement).

The public deserves meaningful information about the price of their hospital care. Hospitals are committed to sharing information that will help the public make important decisions about their health care. Sharing pricing information, however, is more challenging because hospital care is unique. Hospital prices can vary based on patient needs and the services they use; prices reflect the added costs of hospitals' public service role – like fire houses and police stations – serving the essential health care needs of a community 24 hours a day, seven days a week; and most hospitals cannot yet provide prices that reflect important information from other key players like the price of physician care while in the hospital or how much of the bill a patient's insurance company may cover. But more can, and should, be done to share hospital pricing information with consumers.

Providing meaningful information to consumers about the price of their hospital care is the most significant challenge hospitals, and CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;

- Making information easy for consumers to access;

- Using common definitions and language to describe pricing information for consumers;

- Explaining to consumers how and why the price of their care can vary; and

- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

Hospitals in North Carolina already support transparency. We have mandated reporting of inpatient data to an independent agency which provides to the public our top 35 DRGs. Hospitals are willing to work in many ways to inform the public of the cost of healthcare at each facility. However, as much as CMS is concerned about what hospitals and physicians charge for services, consideration should be given to the cost of supplies as well as services coming from vendors for which government provides little-to-no controls. If Medicare continues to cap the increase to providers at CPI-Medical, then the cost which suppliers charge for goods and supplies needs to be capped at a similar level.

Thank you for considering NCHA's comments to the FY 2007 proposed inpatient PPS rule. If you have questions regarding NCHA's comments, you may contact Amelia Bryant at (919) 677-4225.

Sincerely,

NORTH CAROLINA HOSPITAL ASSOCIATION

Millie R. Harding
Senior Vice President

110

CARDIOVASCULAR ASSOCIATES, P.C.

JOHN D. ALTMAN, M.D.
CLAUDIA K. BENEDICT, M.D., F.A.C.C.
JOHN T. FERRELL, M.D., F.A.C.C.
NATHAN GREEN, M.D.
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June 8, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Docket Number: CMS –1488-P

Dear Dr. McClellan:

Cardiovascular Associates, P.C. (CVA) appreciates the opportunity to submit comments related to the proposed 2007 Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Prospective Payment System (IPPS), released on April 12, 2006 and published in the *Federal Register* on April 25, 2006. Our comments are submitted on behalf of all cardiologists in our group.

CVA is a specialty group of 17 cardiologists, interventionalists, non-interventionalists, and electrophysiologists located in Denver, Colorado. A significant proportion of our patients are insured by Medicare and we provide cardiovascular services at five hospitals in the Denver metropolitan area. We have no affiliation with any specialty hospital. The proposed changes will negatively impact our ability to provide high-quality, innovative care and may limit access to care for Medicare beneficiaries.

We appreciate the considerable effort you and your staff members have put into the development and improvement of the inpatient prospective payment system (IPPS) and specifically recognize the need to continually evolve the payment system to reflect the current landscape within the field of medical services. We further recognize the

significant complexities associated with gathering reasonably accurate cost data – data that should serve as the foundation of payment systems such as the proposed IPPS.

Origins of the Proposal

CMS is proposing to make the most significant changes to the hospital inpatient payment system since the late 1980s. The proposed changes appear to have their roots in the Medicare Payment Advisory Commission's (MedPAC) 2005 Report to Congress on Medicare payments for a certain subset of "specialty" hospitals. The MedPAC report raised concerns that the specialty hospitals were selecting the most profitable cases in their area and leaving the other acute care hospitals with less profitable services. Rather than addressing this issue of specialty hospitals in independent fashion, MedPAC recommended changing the payments for ALL acute care hospitals to reduce the incentives in the overall inpatient payment system that fueled the growth of specialty hospital facilities.

CMS should certainly weigh the issues and concerns raised in the MedPAC report when considering policy changes. However, the proposed changes to the inpatient payment system are the equivalent of throwing the baby out with the bath water. Efforts to address issues identified in the MedPAC report should begin and end with the specialty hospital subset and should not occur in conjunction with payment systems at large for all other hospital facilities.

Issues with the proposed IPPS

Setting aside the issues associated with specialty hospitals, ACCA notes two major areas of concern with the proposed IPPS. First, the proposal incorporates an estimated "cost-based" system, rather than a charge-based system for determining the payment weights for each patient category in 2007. Second, the proposal endeavors to change the method of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Proposing both changes in a single regulation, with implementation in 2007, is unprecedented.

Estimated, not Actual, Costs

CMS proposes to base payments on "costs". In many senses, this is a positive move and is consistent with how private insurers handle costs associated with technology. However, the primary difference between CMS's proposed methodology and the private insurers is the timing of cost data. Private insurers are utilizing data in real-time and are paying actual invoice costs for technology used in the care of patients. In CMS's proposal, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat patients, rather it is a rough approximation of costs. To calculate the cost estimates for Fiscal Year 2007 payments, CMS proposes to utilize hospital claims data from Fiscal Year 2005 and

hospital cost reports from Fiscal Year 2003. The cost reports provide the actual costs and the actual charges for all patients (non-Medicare and Medicare patients). The use of any data from Fiscal Year 2003 fails to account for current technology costs – namely drug-eluting stents and bi-ventricular pacemakers/defibrillators, mainstays in the cardiac care landscape. As such, the estimates on cost that CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for the care of Medicare patients.

It is widely known that hospitals across the country do not use a uniform approach to mark-up strategies for technology. Higher cost technologies, such as those used in the treatment of cardiac patients, are often marked up a lower rate than lower cost items. This leads to an inappropriate reflection of cost when attempting to apply derived averages. The following table demonstrates this principle and points out that high-cost technology such as defibrillators and drug-eluting stents would be unfairly accounted for in the proposed reimbursement methodology, causing hospitals to lose substantially with these technologies. This example also highlights why cost reports were never intended to be utilized for the sake of developing accurate procedure specific payment rates.

Gross Impact on Cardiac Care

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

These proposed reductions to cardiac services are severe and are not rooted in any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to pursue a better understanding of actual costs to treat cardiac patients, any such efforts must be made with the intention of producing accurate information – the end result may well be an alteration in the existing infrastructure for cardiac services reimbursement. However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be grave and may potentially limit patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). This is clearly not what CMS intends to achieve with this proposal. As such, delaying the implementation of any changes to cardiac services reimbursement until such time as accurate and appropriate information regarding costs to treat and manage patients with cardiovascular diseases can be compiled is the only prudent approach that can be taken.

Summary

We appreciate the opportunity to provide comments on the proposed CMS IPPS changes. We support CMS's goal of aligning payments with the costs of providing services to

patients and we recognize the extremely complex issues involved in establishing appropriate reimbursement for inpatient procedures. However, we strongly oppose the use of outdated data by CMS to justify substantial payment reductions to hospitals as this will limit our ability to deliver the high quality, innovative care that our patients deserve.

Sincerely,

Donald C. Thompson, MD, FACC
Medical Director/Managing Partner
Cardiovascular Associates, P.C.

Cc: CVA Physicians
DCT/pjs

111

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a Johnson & Johnson company

June 9, 2006

Via Federal Express

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1488-P
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates, CMS-1488-P

Dear Dr. McClellan:

Cordis Corporation is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Medicare Hospital Inpatient Prospective Payment System (PPS) and Fiscal Year 2007 Rates published on April 25, 2005 in the Federal Register. Cordis Corporation is a member of the Johnson & Johnson family of companies and a leading manufacturer of cardiovascular, endovascular, electrophysiology and neurovascular advanced medical technologies.

Johnson & Johnson has already submitted extensive comments discussing CMS' proposed changes with respect to the (1) methodology used to calculate the diagnosis-related group (DRG) relative weights, (2) charge compression and (3) changes to the DRG classification system to better account for patient severity (Johnson & Johnson letter from K. Buto to CMS dated June 9, 2006). Therefore, Cordis' comments will principally focus on the impact of CMS' proposed changes on patient access to advanced technologies for the treatment of circulatory diseases.

A. HSRVcc Payment System

Cordis supports CMS' proposal to improve the accuracy of the hospital inpatient payment system, and we would like to work with CMS to achieve this goal. However, we are concerned that the methodology CMS has chosen has a number of serious flaws, such as using unweighted means for calculating the CCRs and a trimming methodology that omitted charges from 238 large hospitals with high routine care charges, thereby overestimating the CCR for routine costs and underestimating the CCR for ancillary services. These charges were, however included in the DRG weights. We believe that inaccuracies in the hospital cost reports combined with CMS' flawed methodology will, in fact, create a less equitable

and less accurate payment system than the one currently in place. This is, in fact, a "cost-based" system in name only and not one that reflects the true costs incurred by hospitals.

Recommendations

1. Correct the flawed methodology set forth in the proposed rule and request public comment before implementing any changes to the current payment system.

2. Withdraw the proposal to use national average cost-to-charge ratios to estimate costs and move to the use of hospital-specific CCRs as is currently being done in the hospital outpatient prospective payment system.

3. Delay the proposal to combine a hospital-specific relative value (HSRV) methodology with cost-based weights (HSRVcc) until further analysis is conducted of the impact and interaction with cost-based weights.

4. Establish an expert panel to examine the hospital cost reports and to recommend specific changes to improve the accuracy of a cost-based DRG system. The panel should make its recommendations no later than April 2007.

5. Delay implementation of the proposed change to cost-based weights for one year, or longer if necessary, to allow time to explore alternative methodologies and provide stakeholders with an opportunity to study the impacts carefully.

6. Given the importance and magnitude of a change to cost-based weights and the potential impact on hospital finances, Cordis feels that a transition period is necessary to assure that cost-based weights are phased-in smoothly and without any disruption to medical care. If the concerns expressed above can be resolved, Cordis recommends a 4-year transition beginning in FY 2008. This transition would be a stepwise progression of charge and cost-based weights with a complete change to cost-based weights effective in FY 2011.

B. Charge Compression

For several years, AdvaMed and medical device manufacturers have expressed concern that "charge compression" has a negative impact on CMS' ability to establish accurate payment rates for DRGs in which high cost, advanced medical technology is used. The negative impact of "charge compression" is exacerbated by the proposed change to cost-based weights.

Recommendations

1. Cordis recommends that CMS make use of the SAF file to analyze the relationship of revenue codes 275 (pacemakers) and 278 (implantable devices) to non-implantable supplies and equipment. Using these findings, CMS should apply an appropriate adjustment factor to the cost center for medical – surgical supplies (270) in the MedPAR file. In this way CMS will be able to adjust for the lower mark-up that hospitals traditionally apply to high cost implantable devices in contrast to lower cost supplies instead of incorrectly assuming that all medical and surgical devices and equipment have a similar mark-up.

2. Consider a longer term and more permanent solution by creating a separate cost center for implantable devices, thereby eliminating the need for a separate analysis of the SAF file.

3. Issue more explicit guidelines to hospitals to standardize completion of the cost report and thereby increase its accuracy and reliability for payment purposes.

C. Consolidated Severity- Adjusted DRGs

Cordis appreciates the value of a DRG classification system that recognizes the increase in hospital resources needed for treating more severe patients and the goal of adjusting DRG payments to reflect the costs incurred. Unfortunately, CMS' proposal does not describe how they intend to factor in the adjustments and improvements they've made to the DRG system over the past several years to reflect the use of medically advanced technologies (complex procedures) or how they will be accounted for in this new system. Cordis does not see any justification for discarding the current system that has undergone many changes and refinements over the past 21 years. It would be better for CMS to adjust the current DRG structure to accommodate a severity adjustment rather than change to a new system and lose the refinements made through many years of experience.

Recommendations

1. Consolidated severity-adjusted DRGs are not ready for implementation in FY 2007.

2. Cordis supports retaining the current DRG classification system and refining it to adjust for patient severity according to Major Disease Classifications (MDCs) or possibly categories of DRGs, similar to the recently implemented MCVs for cardiovascular DRGs, in contrast to the generic list of complications and co-morbidities (CCs) currently in use that apply to all DRGs. This refined DRG classification system should also identify the complexity of the treatment provided. Payment levels should reflect both patient severity and complexity.

3. Before implementation, CMS should analyze the impact of changes to the DRG system in conjunction with any change to cost-based weights and make this information available to stakeholders well before the proposed rule and in sufficient time for stakeholders to study the impacts carefully.

4. Implement the change to cost-based weights and severity-adjusted DRGs simultaneously to minimize the whipsaw effect to hospital payments that will occur if they are implemented separately. If the above recommendations are addressed, implementation could begin in FY 2008. The change to cost-based weights should be phased-in over 4 years, while the change to severity-adjusted DRGs could be fully implemented in 1 year.

D. Carotid Stenting

The current assignment of carotid stenting to DRGs 533 and 534 does not provide adequate payment for this procedure as allowed under the National Coverage Decision (NCD) issued in March 2005. Although length of stay and operating room costs are lower for carotid stenting, supply and radiology charges associated with the stent and the angiography are significantly higher, resulting in higher overall costs for carotid stenting. Because the NCD specifies the patient population for which

Medicare will pay for carotid stenting as one of high severity at risk for surgical endarterectomy, carotid stenting may be the only viable option for treating carotid artery stenosis in this patient cohort. CMS suggests the cost differences will be addressed with adoption of a consolidated severity adjustment methodology, but also admits the proposed severity adjustment does not currently accommodate patient complexity like that associated with carotid stenting.

Recommendations

1. CMS should create a new pair of DRGs for carotid stenting with and without MCVs until the adequacy of payment under the severity adjustment methodology is fully assessed.

2. If a new pair of DRGs for carotid stenting is not created, CMS should assign all carotid stent cases to DRG 533.

E. Hospital Quality Indicators – Value-Based Purchasing

We applaud efforts by CMS to measure and report on quality indicators. Section 5001(b) of Public Law 109-171 requires CMS to develop a plan to implement hospital value-based purchasing beginning in FY 2009. We encourage CMS to focus on outcome-based rather than process-based indicators of quality.

Recommendation

1. Cardiac services such as PTCA with stenting and bypass surgery provide a potential opportunity to move to outcome-based indicators. We encourage CMS to partner with experts in cardiovascular services to define severity adjustments and evaluate outcome measures for these cardiovascular procedures.

Detailed Comments

I. Hospital-Specific Relative Value Cost Center (HSRVcc) Weighting Methodology

Since 1986 CMS has used a charge-based methodology for determining DRG relative weights and the corresponding payments to hospitals. While not perfect, this system is able to use relatively current charge data, and it has evolved over time to improve the accuracy of payments relative to costs and resources consumed. CMS is proposing to change to a system using cost-based weights. However, since its introduction in 1965, the hospital cost report has undergone very few changes. It was not designed for, and is not compatible with, the calculation of cost-based weights. The result is a very inaccurate estimate of the actual costs.

On at least two occasions, the Prospective Payment Advisory Commission (ProPAC) expressed concerns about using cost-based weights to establish payment rates. In their 1988 report to Congress, ProPAC stated that the "cost report data may, in some cases, produce imprecise DRG weights" and that the "Secretary should verify the accuracy of cost report data and implement changes as necessary."

These concerns were repeated in a 1993 report[1] in which ProPAC states that "The cost report's reliability is reduced considerably when routine inpatient costs and ancillary costs are analyzed separately" and the cost report data "are clearly not reliable or accurate for analyzing micro-level costs."

The change to cost-based weights proposed by CMS will almost certainly have significant and unintended consequences to patient care and patient access to beneficial advanced technology.

In the proposed rule, CMS uses national geometric mean CCRs for each of 10 cost centers. These means are unweighted and therefore do not account for the varying amount of Medicare charges each hospital contributes to total charges. As a result, very small hospitals individually have as much impact on the mean CCRs as larger hospitals. Mathematically, the only correct way to get from total hospital charges to total hospital costs is to use a charge-weighted average of the hospital CCRs. Therefore, applying these un-weighted ratios to charges does not produce an accurate estimate of the national average cost per case.

CMS trimmed the cost center CCR calculation at 1.96 standard deviations from the geometric mean. This systematically excluded hospitals with high markups on routine accommodation charges from the CCR calculation. The CMS trim excluded 238 large hospitals that together accounted for 25 percent of total routine accommodation charges. However, the CCRs for these hospitals appear to be predominantly correct. In addition, the charges for these hospitals are included in calculating the cost center DRG weights despite being excluded from the calculation of the average CCR. The result is a significant mismatch between the CCRs and the pool of charges to which they are applied.

[1]Ashby, J, "The Accuracy of Cost Measures Derived From Medicare Cost Report Data", Prospective Payment Assessment Commission, Intramural Report I-93-01, March 1993.

CMS' proposal to use cost-based HSRVcc weights is unintentionally biased to reward procedures with low medical device (ancillary) costs and long lengths of stay (routine care). Of particular concern is the drastic payment reduction for drug-eluting coronary stents in contrast to the more modest reduction for coronary bypass surgery. This is just one example to illustrate the radical disruption that may take place in the treatment of patients with coronary artery disease, the number one killer of men and women in the US and other western societies.

Furthermore, the cost data used are from FY 2003 while the claims data used are from FY 2005, creating a mismatch in timing of the data. Drug-eluting stents, an important breakthrough in cardiology, that have reduced the need for repeat revascularization by over 70% compared to the previous bare metal stent technology and led to a further reduction in the need for open heart surgery, were only introduced in the latter half of FY2003. Thus, this technology that is now used in over 80% of angioplasty procedures is markedly underrepresented in FY 2003 financial data. Any system that uses data that are 3-4 years old will likely not reflect true costs that are both current and relevant.

While clinical trial outcomes data clearly demonstrate the patient benefits of drug-eluting stents, CMS' proposal may begin to reverse the trend toward less invasive therapies by penalizing hospitals for treating patients receiving less invasive, shorter stay stent procedures and rewarding them for choosing to perform more invasive, more costly and longer length of stay major surgical procedures. (Figures 1-5)

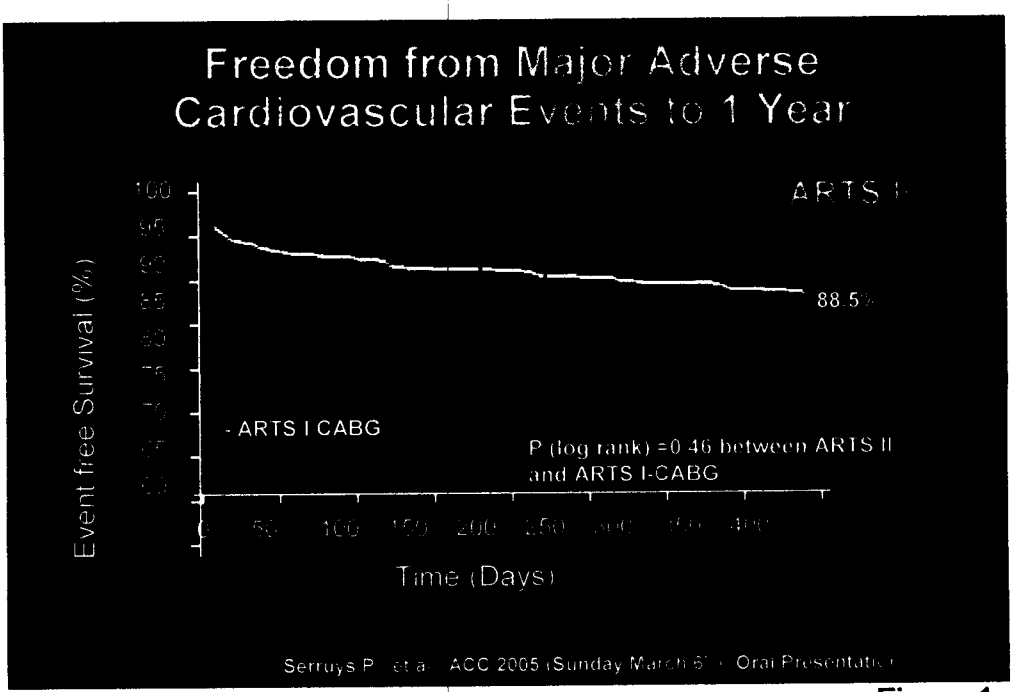
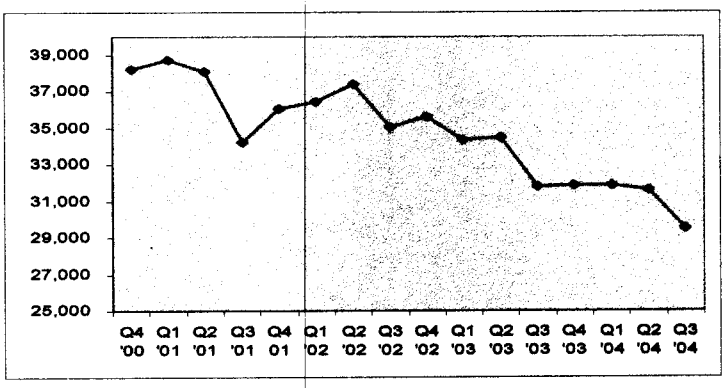


Figure 1

As shown in Figure 1, clinical outcomes data support the trend toward an increase in stenting versus coronary bypass surgery. One year clinical data from the ARTS II trial demonstrate that the CYPHER® drug-eluting stent (DES) is as effective as coronary bypass surgery (CABG) at one year with much less trauma. In the drug-eluting stent arm of the ARTS II trial, 89.5% of the patients had no major cardiovascular events (death, stroke, myocardial infraction or repeat procedure) at the end of one year as compared to 88.5% of the patients receiving CABG. This study will continue to follow patients out to five years.

CABG Medicare Discharges Have Declined...

Medicare CABG Discharges by Quarter FY 2001 - 2004



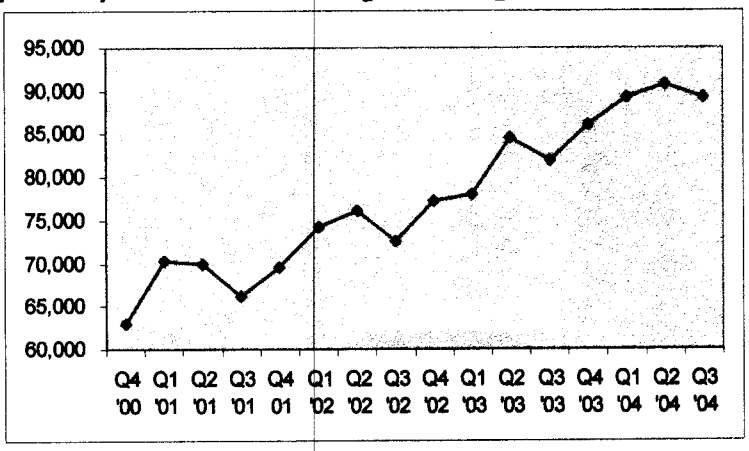
Note: Discharges in DRGs 106, 107 & 109

Figure 2

Even though the incidence of coronary artery disease has remained relatively constant, the number of CABG procedures in the Medicare population has been steadily declining.

As Stenting Has Increased Over the Same Period

Quarterly Medicare Stenting Discharges FY 2001-2004



Note: Discharges in DRGs 516, 517, 526 & 527. Majority of cases in DRG 516 are stenting cases).

Figure 3

In contrast, during this same period (2001 – 2004) the number of coronary stent procedures has increased at a similar rate. This change is a result of clinical data demonstrating the benefits of coronary stents as well as patient and physician preference for a less invasive alternative to CABG, a shorter length of stay and shorter recovery period.

CABG vs. Stent Angioplasty Under the FY 2007 Proposed Rule

	CABG 1/	Angioplasty/ Stenting 2/
Surgical Approach	Invasive Open Heart Surgery	Minimally Invasive Intervention
Mean LOS (FY05)	9.4 Days	2.9 Days
FY06 Base Payment	$25,003	$12,556
FY07 Proposed Reduction	**-4.7%**	**-28.9%**
FY07 Base Payment after reduction	**$23,833**	**$8,931**

1/ Weighted-average figures for CABG DRGs 547, 548, 549 and 550

2/ Weighted-average figures for DRGs 555, 556, 557, 558

Figure 4

Proposed Payment Reductions for Coronary Stent and Coronary Bypass DRGs		
DRG	**Description**	**% change v. FY 2006**
555	Percutaneous Cardiovascular Procedures with MCV	- 21%
556	Bare Metal Stent without MCV	- 34.1%
557	Drug Eluting Stent with MCV	- 23.5%
558	Drug Eluting Stent without MCV	- 33.4%
518	EP Procedures without Stent	- 28.9%
DRG	**Description**	**% change v. FY 2006**
547	CABG with Cardiac Catheterization with MCV	- 5.4%
548	CABG with Cardiac Catheterization without MCV	-8.8%
549	CABG without Cardiac Catheterization with MCV	-1.3%
550	CABG without Cardiac Catheterization without MCV	- 1.4%

Figure 5

In figures 4 and 5 above, it is clear that CMS' proposed change to cost-based weights will have a significant negative impact on the payment rate for coronary stent procedures and only a modest impact on CABG. It will also have a negative impact on the diagnosis and treatment of cardiac arrhythmias using catheter mapping and ablation (electrophysiologic) procedures as opposed to open-heart surgical procedures. This change in payment could have a major unintended and disruptive impact on patient care since it would provide a major disincentive for hospitals to treat patients with coronary artery disease or cardiac arrhythmias by less invasive procedures.

In summary, the proposed HSRVcc weighting methodology has several serious methodological flaws, which need to be corrected (unweighted means and trimming methods). However, even with these corrections, it is questionable whether this method will lead to more or possibly even comparable accuracy to the current charge-weighted method. Hospital cost reports are only estimates of costs, and they provide information that is several years older than the currently used claims charge data. Also, cost reports were not designed to measure case-specific costs, and large parts of the cost reports (including those parts used to calculate cost-based weights) have not been audited for many years.

It is Cordis' position that CMS is moving too quickly to change from an established payment system to one that may be less accurate and may be fraught with serious and unintended consequences to patient care.

II. Charge Compression

Charge compression continues to be a major problem and one whose magnitude is increased by changing to cost-based weights. Since introduction of the Prospective Payment System for hospital outpatient services in 2000, AdvaMed and medical device manufacturers have expressed concern about the impact "charge compression" (higher cost devices being marked up at a lower percentage than lower cost supplies and equipment) is having on the accurate calculation of hospital payments. While this issue is also apparent with a charge-weighted DRG payment system, it is exacerbated if CMS changes to a cost-based system.

Under contract to the Medicare Payment Advisory Committee (MedPAC), The Lewin Group reported their findings of charge compression in a study titled, *A Study of Hospital Charge Setting Practices,* dated December 2005. The Lewin Group states in their report that "Most hospitals reported that higher cost procedures and items generally are assigned a lower mark-up. Hospitals reported charges for supplies being based on a flat percentage or a sliding scale table based on ranges of the costs for each item. For instance, any supply costing less than $100 might be marked up by a certain percentage, while supplies costing over $5,000 would be marked up at a lower percentage as provided in the supply cost table. All but one hospital indicated it marked up lower cost supplies at a higher rate than more expensive supplies."

Data have also been provided by AdvaMed and manufacturers to CMS and to MedPAC demonstrating this fact and even showing that in some cases very high cost items such as implantable cardio-defibrillators (ICDs) may be charged at 100% of cost as compared to lower cost items that receive a 300-400% mark-up.

It is clear that CMS' proposal to aggregate medical supplies, devices and equipment into one cost center (27X) without an appropriate adjustment for the charge compression associated with implantable medical devices (revenue codes 275 and 278) cannot provide an accurate estimate of costs.

III. Consolidated Severity-Adjusted DRGs

CMS is proposing a fundamental change to the DRG structure. While Cordis supports the concept of severity-adjusted DRGs, we are concerned that this change may be disruptive and result in numerous DRG assignment mismatches and significant changes to hospital payments. In addition, we are concerned that an APR-type approach will not incorporate the numerous improvements and refinements that CMS has made over the years to adjust DRG weights to reflect the cost of technological advancements. One example of this refinement was CMS' decision to increase payments for drug-eluting stents by creating two unique DRGs. This change was made by CMS in order to recognize the substantial patient benefits and increased procedural costs associated with the use of these devices. The proposed change to consolidated severity-adjusted DRGs would eliminate the distinction accorded to drug-eluting stents. In the new DRG Grouper, bare coronary stents, drug-eluting coronary stents, balloon angioplasty and electrophysiology would all be assigned to the same series of severity-adjusted DRGs even though these cases have very different costs/charges. This has the potential to unintentionally influence medical practice on the basis of reimbursement rather than the most appropriate treatment for a patient.

Other examples include the creation of new DRGs for ICDs and for use of rtPA (ICD-9 code 99.10) for the treatment of stroke. CMS' proposal does not indicate how or if these changes will be incorporated into the consolidated severity-adjusted DRG structure.

While CMS has suggested the need for a complexity adjustment in addition to a severity adjustment, they have not yet put forth a specific proposal as to how they intend to implement this provision. Cordis agrees with CMS, for the reasons cited in the Proposed Rule, that a change to severity-adjusted DRGs is premature. For CMS to introduce such a significant change without a specific proposal and the ability of stakeholders to have sufficient time to evaluate its strengths and weaknesses is completely unacceptable. Cordis believes that a more straightforward approach to achieving the same or similar objective would be for CMS to keep the current base DRGs (eliminating the current paired DRGs with and without CCs) and adding 3-4 levels of severity to each. This would preserve the adjustments already incorporated into the DRG system and yet adjust hospital payments to reflect the cost of care based on severity of the patient.

IV. Carotid Stenting

The current assignment of Carotid Artery Stenting (CAS) cases in DRGs 533 (extracranial procedures with comorbidities or complications) and 534 (extracranial procedures without comorbidities or complications) which primarily contain surgical carotid endarterectomy cases today, does not provide adequate payment for CAS. The CMS coverage decision of March 17, 2005 defines the appropriate patient population as one at high risk (with high severity lesions, symptoms, and risk factors for surgical endarterectomy). The current inadequate payment rates under DRGs 533 and 534 do not align payments with the cost of providing this safe and effective treatment to this high-risk population, potentially limiting access to treatment for patients with clinical or anatomical conditions that make CAS the only treatment option.

For those patients at high-risk for surgical endarterectomy, extracranial carotid stenting with embolic protection (procedure code 00.63) is a safe and effective alternative at least as good as and often superior to CEA. Available clinical data indicate CAS has similar or lower Major Adverse Event rates (MAE -Death, Stroke, Myocardial Infarction) and significantly fewer cranial nerve palsies and target vessel revascularizations (TVR). In addition, strokes occurring with stenting and embolic protection tend to be minor, as opposed to those occurrences with open CEA that tend to be major events. Data from our clinical trials indicate that the majority of minor strokes resolve without additional treatment. The longer-term benefits and durability of CAS are evidenced in recently released three-year data from the SAPPHIRE trial.

The safety and efficacy of CAS has been reaffirmed with the recently released AHA/ASA Stroke Guidelines that indicate CAS is not inferior to endarterectomy and may be considered for patients with severe symptomatic stenosis that are at high risk for surgery or have other complicating circumstances such as radiation-induced stenosis or restenosis after CEA. The Stroke Guidelines closely parallel CMS' coverage decision on CAS. Cordis Corporation applauds CMS' decision to establish a favorable coverage policy (March 17, 2005) for symptomatic patients and we continue to support CMS' initiative to establish an evidenced based approach in reviewing emerging technologies.

Significant charge differentials between CAS and CEA - Charge differentials have continued to increase in DRGs 533 and 534. Our review of the most recent Premier hospital data through September 30, 2005 continues to demonstrate higher charges and costs for CAS patients compared to non-stented cases in DRGs 533 and 534. Charge data for 2004 from Premier and MedPAR indicate that charges are somewhat comparable with the overall Premier charges being slightly higher. Table 2 summarizes the charge differentials between CAS and CEA for DRGs 533 and 534:

Table 2 – Non-standardized Charge Data for DRGs 533 & 534 – Principal Diagnosis Code = 433.10:

FISCAL YEAR ENDED / SOURCE	DRG 533			DRG 534		
	CAS	CEA	Difference	CAS	CEA	Difference
Fiscal Year Ended September 30, 2004 / MedPAR	$ 35,961	$ 23,294	$ 12,667	$ 27,042	$ 16,58(	$ 10,462
Calendar Year Ended December 31, 2004 / Premier	$ 36,558	$ 22,278	$ 14,280	$ 28,995	$ 16,219	$ 12,776
Year-to-Date September 30, 2005 / Premier	$ 37,351	$ 22,853	$ 14,498	$ 29,419	$ 16,64-	$ 12,775

It is important to note that only 76% and 77% of CAS cases in DRGs 533 and 534 respectively, had device charges coded. This is likely due to clinical trial activity, as anecdotal reports indicate some companies provide carotid stents and embolic protection devices free of charge. Adjusting for the estimated missing charges increases the differential in DRG 533 from $ 14, 498 to $15, 900 ($ 1,402 increase) and in DRG 534 from $ 12,775 to $ 14,100 ($ 1,325 increase).

In the FY 2007 IPPS Proposed Rule, CMS summarizes an analysis of the 2005 MedPAR data indicating shorter length of stay but higher charges for carotid stenting cases compared with those for DRGs 533 (+ $6,986) and 534 (+ $7,804). These charge data suggest underpayment for carotid stenting in both DRGs, but CMS suggests this may be due to higher device mark-ups rather than increased procedure costs. This is a tenuous argument at best, and CMS provides no evidence to support this assertion. This question can, however, be addressed in the context of the proposed HSRVcc DRG re-weighting method proposed by CMS by examining the cost center distributions for the different procedures.

In order for the HSRVcc methodology to provide appropriate payment, the distribution of costs by cost center should be similar for all cases within the individual DRG. The table below breaks down the cost center contributions for DRGs 533 and 534 as well as for cases within these DRGs with and without stenting. Costs are then applied to show how each cost center contributes to the overall cost of cases. As can be seen, this method

suggests supply costs account for a $4,004 difference between carotid stent and non-stent cases in these DRGs. In addition, radiology costs are about 33%, or $1,018 of the total cost difference for stented and non-stented cases. This breakdown shows that carotid stent cases cost more in radiology, cardiology and supplies, which is a reflection of the procedural differences and requirements. Radiology costs are three times greater and supply costs four times greater for stented cases. Non-stented cases require more routine and ICU care, drugs, OR and lab costs. In fact, if CMS believes stent charges are the source of charge differentials, the HSRVcc methods applied to the data suggest a supply cost difference of $4,004, which is approximately equal to the market cost of a carotid stent and embolic protection device, and probably does not account for all additional wires, catheters and supplies. This analysis suggests that stent charges are not the source of higher costs.

Analysis of Cost Center Contribution

Cost center	DRG 533Costs	DRG 534 Costs	No carotid stent cost	Carotid Stent cost	Difference
Routine	$1,574	$722	$1,231	$832	$399
ICU	$3,037	$1,733	$2,690	$2,344	$347
Drugs	$837	$496	$748	$606	$142
Supply	$1,480	$1,102	$1,296	$5,300	-$4,004
Therapy	$278	$55	$209	$158	$51
O.R.	$3,336	$3,092	$3,614	$2,455	$1,159
Card	$204	$82	$153	$432	-$279
Lab	$499	$250	$426	$313	$113
Rad	$694	$355	$519	$1,537	-$1,018
Other	$435	$164	$351	$379	-$28
	$12,373	$8,052	$11,236	$14,355	-$3,119

MedPAR 2005

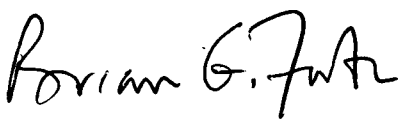
CMS suggests the additional cost of the technology will be addressed with further refinements to the severity-adjusted DRG system proposed. CMS has already acknowledged the inadequacy of the proposed severity-adjustment methodology for dealing with the complexity associated with advanced medical technologies. However, deferral is not a solution to the current inadequate payment for carotid stenting in the absence of more specific details about the proposed system and timelines for implementation.

For many patients, existing co-morbidities and/or anatomical features make carotid stenting the only treatment option. In the absence of adequate payment, many high-risk surgical patients without alternative treatment options may not have access to the procedure. We urge CMS to create a new pair of DRGs for carotid stenting to establish more clinically coherent cohorts that will better align costs of care with payment. If this cannot be done, all carotid stenting cases should be assigned to DRG 533.

CONCLUSION

In conclusion, we support CMS' intention to create a more accurate and more equitable hospital inpatient payment system. We appreciate all of the thought and effort that has gone into CMS' proposal. However, Cordis believes the very substantial proposed change is occurring too quickly and without sufficient time for stakeholders, and possibly even CMS, to fully assess the potential for radical changes in-patient care. We look forward to working together to make sure that the changes that are introduced indeed lead to greater accuracy of payment. These changes need to be phased in over several years so we can monitor the effects on patient care and make appropriate adjustments.

We appreciate the opportunity to comment on the proposed rule.



Brian G. Firth MD, Ph.D, FACC, MBA
Vice President Medical Affairs and Health Economics Worldwide
Cordis Corporation, a Johnson & Johnson Company.

Cc: Marc Hartstein, Deputy Director of the Division of Acute Care (sent electronically)

BRIDGEPORT HOSPITAL
YALE NEW HAVEN HEALTH

June 9, 2006

VIA EXPRESS MAIL
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates"
Proposed Rule Published at 71 *Fed. Reg.* 23995 *et seq.* (April 25, 2006)

Dear Dr. McClellan:

Bridgeport Hospital ("Bridgeport") welcomes the opportunity to submit these comments on the 2007 Inpatient Prospective Payment Systems ("IPPS") proposed rule, published by the Centers for Medicare & Medicaid Services ("CMS") on April 25, 2006 at 71 *Fed. Reg.* 23995 *et seq.* Bridgeport is a nonprofit, 425-bed, tertiary-care teaching hospital located in Bridgeport, Connecticut. Bridgeport Hospital provides nearly 200,000 patient care visits annually, including 20,000 admissions. These comments set forth recommendations and concerns of Bridgeport with respect to: (1) proposed changes to the manner in which diagnosis-related group ("DRG") weights would be derived through a new proposed Hospital-Specific Relative Value cost center methodology; and, (2) a proposal to exclude medical residents' time spent in didactic activities from the calculation of Medicare direct graduate medical education ("GME") and indirect medical education ("IME") payments.

1. Hospital-Specific Relative Value cost center ("HSRVcc") DRG Weights

a. Proposed Recalibration of DRG Weights

The Medicare program currently calculates DRG weights by aggregating the charges for all hospitals paid under IPPS and determining the average charge by DRG. CMS' proposal would revise completely the manner in which DRG weights are calculated, by installing a methodology that groups hospital cost-to-charge ratio data for ten prescribed cost center groups and then applies national average cost-to-charge ratios to eliminate the effect of differential

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charge markups. Bridgeport understands from the preamble to the rule, that this proposal is intended to respond to findings presented in 2005 by MedPAC to Congress that the current charge-based method used by CMS to compute DRG weights has resulted in distorting payments to so-called "physician-owned specialty hospitals" by allowing the assignment of patients with relatively low resource use to relatively high weights and, hence, higher-paid DRGs. We understand the objective of the proposed rule is to repair a perceived vulnerability of the current charge-based weights, which are described in the preamble to the proposed rule as being susceptible to a "practice of differential markups [that] can lead to bias in DRG weights." 71 Fed. Reg. 24007. While one objective of the rule is to address distortions in payment to specialty hospitals, an untoward consequence is to reduce weights and payments significantly for a broad range of surgical cases that are provided in full-service hospitals. The preamble to the proposed rule acknowledges that "[s]urgical DRGs [will] experience a decline of 5.7 percent in weights, while medical DRGs overall increase by approximately 6 percent when we apply the HSRVcc method to the FY6 [*sic*] DRGs." 71 *Fed. Reg.* 24020. Under the proposed rule, there would be an additional change in weights for transplant surgeries since, as noted by the Association of American Medical Colleges, the weights for transplants are overstated because the proposed rule erroneously includes the costs of organ acquisitions, which are paid on a cost basis.

Tertiary care hospitals such as Bridgeport are a primary provider of surgery, and in particular major surgery, for the surgical referrals in their service areas. They also receive a relatively high proportion of major trauma surgical cases that access hospitals on an urgent basis by both helicopter and land ambulance, from a large geographic area. Our review, as set forth in the following comments, finds that significant questions exist as to whether the proposed DRG weights derived by the HSRVcc method are appropriate and accurate to assess resource use for the broad range of surgical cases admitted to full-service hospitals like Bridgeport. While it may be appropriate to implement the proposal for specialty hospitals,[1] we recommend deferral of the HSRVcc methodology for full-service hospitals like Bridgeport to afford more time to study the implications of the HSRVcc as a method of general applicability.

Under the proposed methodology, costs are derived initially at the individual hospital level based on cost-to-charge ratios ("CCRs") for each of the ten cost center groups. The only intensity-related adjustment is to multiply the charge component of the CCR calculated by an individual hospital's case mix index ("CMI"). *See* 79 Fed. Reg. 24008. The summing of national average CMS-adjusted charges for each of the ten cost centers is a key component to establishment of the proposed HSRVcc weights. For several reasons, we believe this methodology understates the medical resources, and hence costs, of tertiary care facilities like Bridgeport for surgical cases.

Recent research has shown that the use of cost-based weights likely is deficient and leads to cost-weight compression, which, in simple terms, refers to the overestimation of the costs of the least sick patients (or cases) and the underestimation of costs of the most sick patients. Botz, Sutherland and Lawrenson, "Cost Weight Compression: Impact of Cost Data Precision and Completeness" (Health Care Financing Review, Spring 2006, Vol. 27, No. 3, at 112). This study goes on to conclude, at page 118, that "hospital funding systems which are based on compressed cost weights will be biased against hospitals with an asymmetrical case mix, that is, hospitals

[1] Congress identified specialty hospitals in Section 507 of Public Law 108-173.

with a disproportionate share of high complexity/high-cost weight cases." This underestimation of the true weight of high-cost surgical cases at tertiary care facilities is borne out by other aspects of the HSRVcc methodology.

The HSRVcc methodology does not appear to account accurately for operating room labor intensity and supplies. Operating room supplies such as cardiac valves, stents, hip and knee prosthetics traditionally are not marked up to the same extent as ancillary services. Moreover, high-cost operating room supplies may be recorded by some hospitals within the medical supplies cost center and by other hospitals in the surgery or other ancillary cost centers. As a result of relatively low mark-ups and a lack of uniformity in cost reporting, these high-cost items appear to be diluted significantly by the HSRVcc methodology.

The proposed methodology also does not recognize the increased costs in surgical cases over medical cases that are applicable to higher routine nursing costs and more intensive ancillary, such as respiratory, services used by surgical cases. As above, the data seem to underrepresent these costs, since hospitals do not mark up high-cost, hands-on services to the extent ancillary services are marked up in non-surgical cases. It is therefore likely that the HSRVcc weights significantly underestimate these costs.

Another important issue presented by the proposed methodology is that providers may not report surgical devices and supplies, among other costs, within the same cost centers on their Medicare cost reports. For example, operating room supplies could be reported in an Operating Room line item or in a Medical and Surgical Supply line item. The misalignment of these costs on cost reports may be distorted further by the inaccurate matching of particular costs with departmental revenues, as different hospitals have different methods for accumulating and assigning charges. This means that there often is a mismatch between the costs and charges used by CMS to develop the national cost-to-charge ratios. The absence of coordination of these costs on cost reports becomes material under the cost-based HSRVcc proposal. In this connection, we note that, especially in the case of non-teaching hospitals – community hospitals which have no or little cost-based payments under IPPS – fiscal intermediaries have not fully audited cost reports and may only have conducted desk reviews over the past several years. The HSRVcc proposal therefore is based largely on unaudited cost data, which forms an inappropriate basis for a broad reduction of weights for surgical cases on a national basis.

Given the number of concerns regarding the HSRVcc methodology, Bridgeport recommends the Secretary delay in moving from a charge-based system to the proposed HSRVcc system. A delay not only would allow for an improvement in data collection, audit and application, it would provide an opportunity for the Secretary to examine areas where resource use is understated by the currently proposed HSRVcc methodology. Alternatively, Bridgeport suggest that CMS revise the rule to include a 3-year phase-in or a 3-year blend, which would apply to all hospitals except for specialty hospitals. This exception may be supported by MedPAC's finding that current charge-based weights can become biased by differential markups, which have been found to be the practice of some specialty hospitals. Given the broad spectrum of services they provide, it would be difficult for full-service hospitals, such as Bridgeport, to engage in the type of differential markups which lead to MedPAC's findings concerning specialty hospitals. As we have stated above, this problem should not be addressed by the

imposition of cost-based HSRVcc-derived weights, which introduce cost weight compression and penalize Bridgeport and similarly-situated hospitals.

b. DRGs: Severity of Illness

CMS is proposing to implement, in FY 2008 if not earlier, a "consolidated severity-adjusted DRG" system (by which it means a system based on a consolidated version of the APR-DRGs designed by 3M Health Information Systems). Bridgeport ask that the Secretary make public the grouper for APR-DRGs so that it may meaningfully comment on this proposal. The DRG grouper currently used by CMS is in the public domain but the APR-DRG Grouper is not. Bridgeport believes it is essential to the public comment process that the APR-DRG grouper or any hybrid model which is proposed to be implemented by the Medicare program be made public. Accordingly, Bridgeport request that the Secretary afford hospitals a new comment opportunity after this grouper is made public.

2. FTE Resident Count and Documentation

a. Background

The preamble to the proposed rule cites medical journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent ("FTE") resident counts for all IME payments (regardless of setting), and for GME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time, is that the time is not "related to patient care." However, Bridgeport concurs with CMS' 1999 position (evident in a letter, dated September 24, 1999, from Tzvi Hefter, the Director of the Division of Acute Care, to Scott McBride of Vinson & Elkins), that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures ... and presentation of papers and research results to fellow residents, medical students, and faculty.". The activities cited in both that letter and the purported "clarification" are an integral component of the patient care activities engaged in by residents during their residency programs.

b. Residency Program Activities and Patient Care

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in GME is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

Bridgeport strongly urges CMS to rescind its purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of GME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Patrick McCabe
Sr. Vice President & CFO
Bridgeport Hospital

113

Dartmouth-Hitchcock Medical Center

Mary Hitchcock Memorial Hospital

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June 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: HSRV Weights

The purpose of this letter is to comment on the Medicare proposed rule concerning the Hospital Inpatient Prospective Payment System as published by CMS in the Federal Register of Wednesday April 25, 2006.

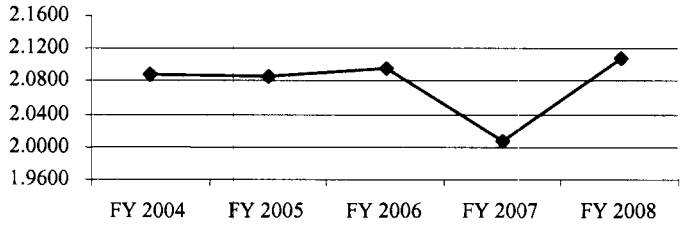
By way of background, the Dartmouth-Hitchcock Medical Center (DHMC) is comprised of Mary Hitchcock Memorial Hospital, a 327 bed teaching hospital, the Dartmouth-Hitchcock Clinic, a large academic group practice, Dartmouth Medical School, and the Veterans Administration Hospital. Mary Hitchcock is the only academic tertiary care hospital in the state of New Hampshire, and is one of only a few major rural teaching hospitals in the country.

We are writing to express our concerns about CMS's proposed adoption of MedPAC's recommended changes to the Inpatient Prospective Payment System. Although we agree with CMS's intention to address the flaws in the current DRG system, we strongly urge CMS to implement the Consolidated Severity Adjusted DRGs concurrently with the HSRV Weights. If these changes cannot be implemented concurrently in FY07, we strongly urge that implementation be delayed until FY08. Our recommendations are similar to those made by MedPAC in a letter to CMS dated April 19, 2006.

CMS has acknowledged that providers that lose under HSRV weights may gain under a consolidated severity-adjusted DRG system. What if CMS had proposed to adopt a consolidated severity-adjusted DRG system in FY07 and the HSRV weights in FY08? Many providers that are disadvantaged under the current proposal would gain under this proposal. We agree with MedPAC that these types of payment shifts are unjustified.

In our own analysis (see below), using data from the FY04 MedPar file, we discovered that our findings were consistent with the concerns addressed by MedPAC. Based on CMS's current proposal, our case mix index would be reduced by 4.6% in FY07 (HSRVs) and would increase by 5.3% in FY08 (new DRGS). The combined impact (FY06 to FY08) would be a .5% increase. Under budget neutrality, our case mix index would increase by 6.1% in FY08 (from FY07) and the combined impact (FY06 to FY08) would be an increase of 1.2%. Under the current proposal we would stand to lose in excess of $5M in FY07 only to gain it back and more in FY08.

Mary Hitchcock Memorial Hospital
Case Mix Index



In addition to the dramatic shifts in provider payments, there appear to be many unanswered questions regarding the proposed rule. Although CMS is committed to adopting a severity adjusted DRG system, they have proposed an array of alternatives. The alternatives range from implementing the 3M APR DRG system in FY08 (or earlier) to considering other severity based DRG systems. There also appear to be proprietary concerns related to the 3M grouper. In addition, the proposed rule provides no information as to how post acute care transfer payments will be impacted by the new grouper and only a limited discussion as to how outliers will be impacted. There are also questions regarding CMS's development of HSRVs, questions that may have been answered if a detailed case study had been made available for comment in the proposed rule.

We are concerned and perplexed by CMS's desire to partially implement a very complex set of policy changes. Many providers will be unjustly disadvantaged by CMS's decision not to implement the policy changes concurrently. MedPAC has clearly stated the objectives of its policy changes. We propose that CMS implement the consolidated severity adjusted DRGs concurrently with the HSRV weights. If the concurrent implementation cannot be done in FY07, we ask that it be delayed to FY08.

Thank you for consideration of these comments.

Sincerely,

RH Showalter

Richard H. Showalter, Jr.
Senior Vice President, Finance

RHS/kn

Dartmouth-Hitchcock Medical Center
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June 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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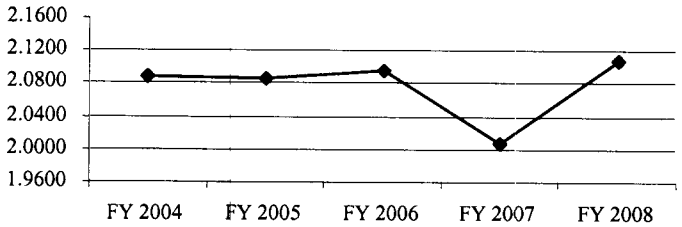

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Sincerely,

Richard H. Showalter, Jr.
Senior Vice President, Finance

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June 9, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
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Re: GME Payments

Resident Time at Nonhospital Settings

In the proposed rule CMS states that it is clarifying its policy concerning the counting of resident time in "nonpatient" care activities at nonhospital settings for purposes of direct graduate medical education ("GME") and indirect medical education ("IME") payments. CMS notes that, "as part of an approved medical residency program, residents are often required to participate in didactic and 'scholarly' activities such as educational conferences, journal clubs, and seminars." CMS then "clarifies" its position that this time cannot be included in the GME and IME resident count at nonhospital settings because it does not involve the care and treatment of a particular patient or billable physician activity.

DHMC disagrees with CMS's restrictive view of what constitutes patient care and asks that CMS adopt a more expansive policy that reflects current trends in patient care and medical training. As CMS states in the preamble to the proposed rule, didactic and scholarly activities are common requirements in residency programs and integral components of graduate medical education. The time that residents spend in didactics is for the purpose of acquiring the skills that are necessary in order to competently provide for the diagnosis and treatment of patients. This time should not be excluded from resident time. It is very relevant to the care of patients. We note that the CMS letter referenced in the preamble states that it "interprets the phrase 'patient care activities' broadly to include any patient care oriented activities that are part of the residency program." Clearly, CMS has the authority to adopt a broader view of patient care activities, as it did in this 1999 letter.

Although CMS states that it is clarifying its existing policy, DHMC believes that CMS is announcing a new policy that cannot be applied retroactively. As CMS states in the discussion, it has received many inquiries on the subject and previously issued a letter stating a contrary policy. The confusion caused by CMS's varying policy statements over the years demonstrates that CMS's purported clarification is really a new policy that should only be applied prospectively.

Finally, DHMC notes that CMS's policy regarding time that may be included in the resident count at nonhospital settings is inconsistent with its policy regarding time for which a hospital must reimburse a teaching physician in those settings. On the one hand, CMS proposes only to count resident time related to direct patient care activities. On the other hand, CMS precludes hospitals

from paying teaching physicians for supervising residents during time spent on direct patient care activities and requires hospitals to pay for teaching supervision during scholarly activities. These conflicting positions result in a policy where hospitals count time for which they don't pay for teaching and don't count time for which they do pay for teaching. This will lead to considerable confusion in the provider community. It will also create administrative burdens and practical difficulties for teaching hospitals in order to differentiate between care related to particular patients and other activities.

DHMC requests that CMS adopt a policy that interprets patient care activities in nonhospital settings to include didactic and scholarly activities, provided they are part of an approved GME program.

Sincerely,

Richard H. Showalter, Jr.
Senior Vice President, Finance

RHS/kn

CATHOLIC HEALTH INITIATIVES

Memorial
Health Care System
MEMORIAL HOSPITAL

June 8, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Comment Period FY 07 IPPS Proposed Rule
Memorial Health Care System #44-0091

Memorial Health Care System urges CMS to delay the current proposal to overhaul the DRG system with a return to the current methodology, until the proposed methodologies and underlying cost data can be improved to ensure the accuracy of payments. Memorial Health Care System urges this delay based on several reasons:

Estimated, not Actual, Costs—CMS proposes to base payments on "costs". However, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat the patients, but rather a rough approximation of costs. To calculate the cost estimates for Fiscal Year 2007 payments, CMS will use hospital claims data from Fiscal year 2005, and hospital cost reports from fiscal year 2003. The cost reports provide the actual costs and the actual charges for all patients (non-Medicare and Medicare patients). However, the cost centers contain products with low costs and high costs. Since hospitals have varying mark-ups, the cost estimations generally underestimate the value of high price items and overestimate the value of low-cost items as illustrated below:

Impact of Assuming Uniform Mark-Up in Estimating Costs – A Hypothetical Example

	Costs	Mark-Up	Charges After Mark-Up	Average Mark-Up for Department	Estimated Costs Based on Average Mark-Up
Medically Advanced Technologies	**$25,000**	200.0%	$50,000	266.7%	**$18,750**
Other Supplies	**$5**	400.0%	$20	266.7%	**$8**

Ten National Cost Groups and Calculation Error--The proposed changes would further distort the estimation of accurate costs by combining multiple costs centers on hospital cost reports into ten CMS-designated cost centers. In the proposed payment system, CMS would calculate ten national average cost-to-charge ratios (CCRs) for each of the designated cost centers. In making the national level calculations, however, the ratios were not weighted by each hospital's Medicare charges. This mathematical error would allow very small hospitals to have just as much impact on the national cost-to-charge ratios as larger hospitals. In addition, hospitals with low mark-ups (high CCRs) would have just as large an impact as hospitals with high mark-ups (low CCRs). If these methodological flaws are corrected, it would produce very different DRG weights and hospital impacts than those published in the proposed rule. CMS should allow adequate time for commenters to analyze these errors, the resulting DRG changes, and hospital impacts before finalizing the regulation.

Lags, Mismatched, and Missing Data-- Moving from charge-based payment weights to cost-based payment weights would introduce additional lags in the data used to calculate rates. The mismatch between the time period for the hospital claims and the hospital cost reports further distorts the calculations. For FY 2007 rates, CMS would use FY 2005 hospital claims. By contrast, cost reports for the calculations would be for periods ending in FY 2003. Many of the new technologies that will be available in FY 2007 will not be included in the claims data nor the cost report data used to calculate payments. Finally, early modeling results suggest that CMS data trimming method excluded 260 large hospitals with high room and board mark-ups (accounting for 25% of routine room and board charges) from the national cost center calculations.

Variation in Hospital Reporting-- Since the implementation of the inpatient payment system, the validity of the cost reporting data has increasingly diminished. In any given time period, the data may be unreported or the cost report may be "unsettled" for a significant portion of hospitals. Approximately 15% of cost reports are audited.

Reforming Medicare's inpatient payment system to provide more accurate rates for hospitals is a laudable goal. But the current proposed rule is deeply flawed. An initial review of the proposed rule has uncovered a number of technical errors or questionable technical decisions. Two of them—the decision to remove 260 large hospitals accounting for 25% of routine room and board charges, and improper weighting of the data used to develop the national cost-to-charge ratios—have a major impact on a number of key DRGs . Replacing the existing system with the one currently proposed by CMS would create even greater opportunities for inaccurate payments. The limited time to review and adjust such a fundamental change raises the possibility of extremely negative impacts on hospitals, patients, physicians, and other key stakeholders.

Again, Memorial Health Care System urges CMS to delay the current proposal to overhaul the DRG system with a return to the current methodology, until the proposed methodologies and underlying cost data can be improved to ensure the accuracy of payments.

Sincerely,

Ruth W. Brinkley

Ruth W. Brinkley
President/CEO

June 9, 2006

Dr. Mark McClellan
CMS Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P and CMS-1488-P-2
Room C4-26-05
Central Building
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1488-P and CMS-1488-P-2

Dear Dr. McClellan:

Meridian Health welcomes the opportunity to comment on the (CMS-1488-P) Centers for Medicare & Medicaid Services (CMS) proposed rule entitled *Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule,* 71 Federal Register 23996 (April 25, 2006) and (CMS-1488-P-2) entitled *Medicare Program; Hospital Inpatient Prospective Payment Systems Implementation of the Fiscal Year 2007 Occupational Mix Adjustment to the Wage Index,* 71 Federal Register 28644 (May 17, 2006).

Meridian Health is a three hospital System located in Monmouth / Ocean Counties in New Jersey. The three acute-care hospitals that comprise Meridian Health are Jersey Shore University Hospital (Provider # 31-0073); Ocean Medical Center (Provider # 31-0052) and Riverview Medical Center (Provider # 31-0034).

The following comments / questions will apply to the various labeled sections from the aforementioned proposed rulings:

- **"DRG Reclassifications":** "Cost Center Charge Group" - Questions in this regard are as follows:
    1. Did CMS study the financial impact of combining multiple cost report cost centers into the ten "charge groups" denoted in the proposed rule? Were there any other combinations reviewed, and if so, were the outcomes similar? CMS should elaborate on the process it went through to derive the ten charge groups?

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2. The proposed methodology assumes that all hospitals map their data consistently within the specified cost centers. An example of the potential mismatch of data is in the Cardiology charge group. Currently, cost centers 53 and 54 are grouped there and many providers have cardiology type services, such as cardiac cath in cost centers other than 53 and 54; therefore, there is a mismatch of data. Another example is cardiac stents, are they being reported in the supply or cardiac cost center? This item in particular could dramatically effect Medicare reimbursement at Jersey Shore University Medical Center (JSUMC). It is unclear if hospitals are reporting these types of items consistently.

3. CMS should publish a crosswalk of revenue codes for the charge side that is used to map Med-Par data to the charge groups and assure that the cost report data utilized has been reviewed by the Medicare fiscal intermediaries to assure consistent reporting taking into account issues as noted above with cardiac stents, etc. (CMS should use final settled cost report data not submitted). The intermediaries should assure that there is consistent revenue code mapping on the cost reports that coincide with the revenue mapping utilized in the Med-Par logic. An alternative would be to establish a mechanism to allow hospitals to review the cost report data being utilized and submit changes, where applicable, to their Medicare fiscal intermediaries for review and implementation.

4. The consolidated severity-adjusted DRG methodology needs to accommodate distinctions based on complexity.

- **"HSRV Weights":** Meridian Health is not opposed to moving from a charge-based weight system to a cost-based weight system; however, we believe the current proposed methodology needs further examination in order to determine the best methodology to develop cost-based weights. The current proposal to use hospital specific departmental costs for the development of the Medicare payment rates will only result in a redistribution of Medicare payments. Since hospital costs within departments are rarely consistent between hospitals, the use of departmental cost to charge ratios is not accurate. Meridian Health requests CMS not implement the currently proposed weight methodology but continue to look for alternatives.

    1. Did CMS consider the mismatch of Med-Par data and cost report data for the following category? If so, the outcome should be reported and if not, this mismatch of data should be analyzed for potential impact on the relative weight calculations:
        - Claims with routine only charges (no ancillary charges) were deleted from the Med-Par data; however, the cost for these claims should be in the cost report data and they may be grouped 100% to routine cost centers on the cost report as well.

2. CMS should not implement the HSRV methodology without the consolidated severity-adjusted DRG methodology. Furthermore, CMS should not implement the severity DRG methodology until the grouper for such DRG system is publicly available for hospitals to properly analyze the impact for comment purposes. In order to analyze and comment, a cross-walk between the current DRGs and the severity DRGs should be made available. Implementing the HSRV weight methodology before the severity DRG system seems to be backwards since a DRG classification takes place before a weight is assigned.

3. Given the magnitude of Medicare payment redistribution, that both the HSRV weight and severity DRG will have on hospitals (along with the occupational mix being implemented at 100%), CMS should give consideration of phasing in the HSRV weighting methodology and severity DRG over a three (3) year transition period. Such an approach would be consistent with other significant changes in Medicare payment methodologies, such as blended rates for psychiatric PPS and a ten year transition for PPS capital.

   To illustrate the Medicare payment redistribution, Meridian Health hospitals are a typical example. All three hospitals are non-profit acute care hospitals. JSUMC is the only major teaching hospital of the three. JSUMC also has an extensive cardiac program. Based on our internal modeling (and validated by a consultant analysis) of the weight changes, the combination of Ocean Medical Center and Riverview Medical Center would gain approximately $2.9 million. JSUMC, however would lose approximately $9.7 million overall. The surgical cardiac DRGs were responsible for a $10.3 million loss. Therefore, you can see the disproportionate redistribution of payments. If JSUMC was not a leading cardiac service provider, they would have gained from the weight changes. CMS needs to further review the proposed methodology when one service is responsible for such significant changes. As stated above, CMS should consider a transition period for the phasing in of the HSRV weighting methodology and severity DRGs.

4. An adjustment to the standardized rates for changes in coding should not be implemented unless there is a reconciliation mechanism in which the estimated amount can be compared to an actual amount and the difference be incorporated in another year's data.

- **Calculation of the proposed FY 2007 occupational mix adjustment":**
  In prior years approximately 425 hospitals did not submit occupational mix data. Meridian Health believes that CMS should hold all Medicare certified PPS hospitals accountable to submit occupational mix data. It should be considered as part of their participation in the Medicare program and anything short of a

submission of occupational mix data should put them in violation of adhering to the conditions of participation with the Medicare program.

- **Occupational Mix "Timeline":**
    1. Hospitals had a short time frame in which to submit data to the intermediaries and the intermediaries have a short time frame in which to review all submitted data and correspond with hospitals to resolve any discrepancies that may be noted during their audit process. It is also unclear how consistent all intermediaries may be in auditing this data. Given this ambitious timeframe, the validity of the data may be questionable and it is certainly prone to have a redistributive impact on Medicare payments (along with the newly proposed DRG weighting methodology and potential severity DRG for FY 2007). CMS should consider deferring the implementation of the newly proposed DRG weighting methodology and potential severity DRG until at least FY 2008 to alleviate the burden on hospitals that will receive redistributive impacts on Medicare payments under the occupational mix adjustment.

    2. Corrected survey data, which is due by July 27, 2006 from the intermediaries, should also be made available via public use files prior to the publication of the final amounts for the inpatient prospective payment system, which is scheduled to be published between the final rule and implementation date of October 1, 2006.

- **"Wage Index"/"Operating Payment Rates":** CMS should propose now to extend the imputed rural floor to coincide with the existence of a rural floor. This would then put all 50 States on a "level playing field." The remaining States, not involved with the imputed rural floor calculation, have been receiving the rural floor benefit for many years and will then continue to benefit in the future.

- **"Outliers":** CMS is currently paying less than 5.1% for outliers (as was the case for FY 2005, as well) and CMS does not currently make retroactive adjustments when total outlier payments that fall below estimated amounts. However, in the proposed FY 2007 rule, the outlier threshold is set to increase based upon "simulations using FY 2005 Medicare data" and the need to ensure that 5.1% of total IPPS payments are paid as outliers. The increase to FY 2007 outlier threshold is inconsistent with the prior two year outlier trend of actual payments falling below the 5.1% target; therefore, CMS should ensure that the final FY 2007 rule includes a reduction to the outlier threshold to preserve hospital's rights to their fair share of outlier payments in the absence of a reconciliation process to the 5.1% target.

- **"GME Payments":** The proposed rule states that resident training that occurs at non-hospital sites must be related to patient care if a hospital wishes to count that time for direct medical education (DGME) and indirect medical education (IME) payment purposes. Resident time spent in didactic activities that often occur in

associated medical schools – such as educational conferences, journal clubs and seminars – would specifically be excluded. CMS noted that its statement in a previous letter on this topic "implying that didactic time spent in non-hospital settings could be counted for direct GME and IME ... was inaccurate." CMS also noted that time spent in these activities could be counted for DGME purposes if they occur in a hospital; however, the counting prohibition applies for IME payments regardless of where the educational activity occurs.

We urge CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic (educational) activities in the calculation of Medicare DGME and IME payments. The stated rationale for the exclusion of this time is that it not "related "to patient care." This position is in stark contrast to CMS' position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures...and presentation of papers and research results to fellow residents, medical students, and faculty."

We agree with CMS' 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. In addition, it would be very difficult to separate out time spent at these activities. CMS should allow the time spent in didactic activities at non-hospital sites as long as a written agreement is in place with the non-hospital site and the hospital incurs "all or substantially all" of the cost since the hospitals are incurring the cost of residents. We urge CMS to withdraw this change in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Thank you for this opportunity to comment.

Respectfully submitted,

Mike Sabo
Meridian Health
Corporate Reimbursement Manager

TEXAS HEALTH RESOURCES

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of Texas Health Resources (THR) and its 13 faith-based, nonprofit community hospitals throughout North Texas, including Harris Methodist Hospitals, Arlington Memorial Hospital and Presbyterian Healthcare System, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the FY'07 Medicare Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 *Federal Register*. Given the complexities of CMS' proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on THR, we are writing to urge a one-year delay in implementing these policy proposals.

CMS proposes to move from the historical charge-based DRG system to a cost-based system and to implement hospital-specific relative weights by October 1, 2006. CMS also proposes modifying the DRG classification system to account for differences in patient severity and allow for a payment amount that more closely tracks the cost of providing care. In its proposal, CMS states that it would replace the current 526 DRGs with either the proposed 861 consolidated severity-adjusted DRGs by FY'08 or a similar system that accounts for the level of patient severity, developed in response to public comments that it receives.

THR supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a DRG system that more accurately reflects the costs of providing inpatient services. We recognize that your agency has taken these steps to make payments fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. Restructuring the DRG system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals.

As such, we strongly urge CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY'08. The additional time will allow THR and

other health systems and hospitals to more thoroughly evaluate the proposals and offer constructive feedback to your agency.

Hospital Quality Data

The Deficit Reduction Act of 2005 (DRA) expands quality reporting requirements for hospitals to be eligible to receive a full market basket update. The proposed rule states that in order to qualify for their full market basket update, hospitals would have to pledge to submit data on all 21 measures currently part of the Hospital Quality Alliance's (HQA) public reporting for patients discharged on or after January 1, 2006.

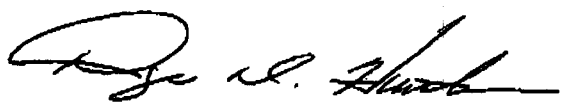
THR appreciates these efforts to make more meaningful and accurate information on hospital quality available to the public. However, the proposed rule, as written, would require the reopening of data files and costly, difficult retroactive alterations—all of which could lead to the introduction of new kinds of errors in the data. As such, we strongly urge CMS to make the data collection prospective—delaying implementation of the expanded set of measures until discharges on or after July 1, 2006. This delay will allow THR and other health systems and hospitals to allocate the required resources for this expanded data collection.

The proposed rule and the Institute of Medicine (IOM) report also discuss three specific measures from The Leapfrog Group—computerized provider order entry, intensive care intensivists, and evidence-based hospital referrals. THR supports consideration of structural measures that meet quality measure standards such as evidence-based, clear operational definitions, delineated process for validation and auditing that ensures reliability and measures an area of quality within the control of the provider. We do not believe the three Leapfrog Group measures discussed in the IOM report meet the quality measure standards necessary for inclusion in CMS' national quality measurement initiatives.

THR agrees with CMS that it is also critical that the collected data be validated. The parameters of the validation process should be stated explicitly and documented. This includes clear definitions, all applicable skip logic, all edits or audits to be applied and other related information. Hospitals must know exactly *what* is being validated so they may adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarter's validation, they have already moved onto the next quarter's data collection and can not make changes quickly enough to impact the next quarter. If the validation specifications and requirements were clearer and well-documented, hospitals could be more proactive. As such, any changes should be communicated clearly and within a timeframe sufficient for hospitals to react and change any processes. THR proposes that any modifications to the technical processes be published at least 120 days prior to the effective/implementation date. Further, THR believes that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period.

Again, thank you for the opportunity to share our comments. We look forward to working with CMS to resolve these issues and concerns. If we can provide you or your staff with additional information, please do not hesitate to contact David Tesmer, Vice President of Government and Community Affairs, at 817-462-7937 or by e-mail at DavidTesmer@TexasHealth.org.

Sincerely,



Douglas D. Hawthorne, FACHE
President and CEO
Texas Health Resources

119

YALE-NEW HAVEN HOSPITAL

June 9, 2006

VIA EXPRESS MAIL
Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates"
Proposed Rule Published at 71 *Fed. Reg.* 23995 *et seq.* (April 25, 2006)

Dear Dr. McClellan:

Yale-New Haven Hospital ("Y-NHH" or the "Hospital") welcomes the opportunity to submit these comments on the 2007 Inpatient Prospective Payment Systems ("IPPS") proposed rule, published by the Centers for Medicare & Medicaid Services ("CMS") on April 25, 2006 at 71 *Fed. Reg.* 23995 *et seq*. Y-NHH is a nonprofit, 944-bed, tertiary care hospital located in New Haven, Connecticut, which serves as a teaching hospital for the Yale School of Medicine. Y-NHH provides over 250,000 days of inpatient care per year and is a major provider of health care services within the State of Connecticut. Y-NHH also provides comprehensive tertiary care services to patients referred to it from throughout the New England region, as well as from foreign countries. The Hospital serves as a statewide resource for Level I Emergency Trauma Services. These comments set forth recommendations and concerns of Y-NHH with respect to: (1) proposed changes to the manner in which diagnosis-related group ("DRG") weights would be derived through a new proposed Hospital-Specific Relative Value cost center methodology; and, (2) a proposal to exclude medical residents' time spent in didactic activities from the calculation of Medicare direct graduate medical education ("GME") and indirect medical education ("IME") payments.

1. Hospital-Specific Relative Value cost center ("HSRVcc") DRG Weights

a. Proposed Recalibration of DRG Weights – We recommend deferral of the HSRVcc methodology for full-service hospitals like Y-NHH to afford more time to study the implications of the HSRVcc as a method of general applicability.

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The Medicare program currently calculates DRG weights by aggregating the charges for all hospitals paid under IPPS and determining the average charge by DRG. CMS' proposal would revise completely the manner in which DRG weights are calculated, by installing a methodology that groups hospital cost-to-charge ratio data for ten prescribed cost center groups and then applies national average cost-to-charge ratios to eliminate the effect of differential charge markups. Y-NHH understands from the preamble to the rule, that this proposal is intended to respond to findings presented in 2005 by MedPAC to Congress that the current charge-based method used by CMS to compute DRG weights has resulted in distorting payments to so-called "physician-owned specialty hospitals" by allowing the assignment of patients with relatively low resource use to relatively high weights and, hence, higher-paid DRGs. We understand the objective of the proposed rule is to repair a perceived vulnerability of the current charge-based weights, which are described in the preamble to the proposed rule as being susceptible to a "practice of differential markups [that] can lead to bias in DRG weights." 71 Fed. Reg. 24007. While one objective of the rule is to address distortions in payment to specialty hospitals, an untoward consequence is to reduce weights and payments significantly for a broad range of surgical cases that are provided in full-service hospitals. The preamble to the proposed rule acknowledges that "[s]urgical DRGs [will] experience a decline of 5.7 percent in weights, while medical DRGs overall increase by approximately 6 percent when we apply the HSRVcc method to the FY6 [*sic*] DRGs." 71 *Fed. Reg.* 24020. Under the proposed rule, there would be an additional change in weights for transplant surgeries since, as noted by the Association of American Medical Colleges, the weights for transplants are overstated because the proposed rule erroneously includes the costs of organ acquisitions, which are paid on a cost basis.

Tertiary care hospitals such as Y-NHH are a primary provider of surgery, and in particular major surgery, for the surgical referrals in their service areas. They also receive a relatively high proportion of major trauma surgical cases that access hospitals on an urgent basis by both helicopter and land ambulance, from a large geographic area. Our review, as set forth in the following comments, finds that significant questions exist as to whether the proposed DRG weights derived by the HSRVcc method are appropriate and accurate to assess resource use for the broad range of surgical cases admitted to full-service hospitals like Y-NHH.

Under the proposed methodology, costs are derived initially at the individual hospital level based on cost-to-charge ratios ("CCRs") for each of the ten cost center groups. The only intensity-related adjustment is to multiply the charge component of the CCR calculated by an individual hospital's case mix index ("CMI"). *See* 79 Fed. Reg. 24008. The summing of national average CMS-adjusted charges for each of the ten cost centers is a key component to establishment of the proposed HSRVcc weights. For several reasons, we believe this methodology understates the medical resources, and hence costs, of tertiary care facilities like Y-NHH for surgical cases.

Recent research has shown that the use of cost-based weights likely is deficient and leads to cost-weight compression, which, in simple terms, refers to the overestimation of the costs of the least sick patients (or cases) and the underestimation of costs of the most sick patients. Botz, Sutherland and Lawrenson, "Cost Weight Compression: Impact of Cost Data Precision and Completeness" (Health Care Financing Review, Spring 2006, Vol. 27, No. 3, at 112). This study goes on to conclude, at page 118, that "hospital funding systems which are based on compressed cost weights will be biased against hospitals with an asymmetrical case mix, that is, hospitals

with a disproportionate share of high complexity/high-cost weight cases." This underestimation of the true weight of high-cost surgical cases at tertiary care facilities is borne out by other aspects of the HSRVcc methodology.

The HSRVcc methodology does not appear to account accurately for operating room labor intensity and supplies. Operating room supplies such as cardiac valves, stents, hip and knee prosthetics traditionally are not marked up to the same extent as ancillary services. Moreover, high-cost operating room supplies may be recorded by some hospitals within the medical supplies cost center and by other hospitals in the surgery or other ancillary cost centers. As a result of relatively low mark-ups and a lack of uniformity in cost reporting, these high-cost items appear to be diluted significantly by the HSRVcc methodology.

The proposed methodology also does not recognize the increased costs in surgical cases over medical cases that are applicable to higher routine nursing costs and more intensive ancillary, such as respiratory, services used by surgical cases. As above, the data seem to underrepresent these costs, since hospitals do not mark up high-cost, hands-on services to the extent ancillary services are marked up in non-surgical cases. It is therefore likely that the HSRVcc weights significantly underestimate these costs.

Another important issue presented by the proposed methodology is that providers may not report surgical devices and supplies, among other costs, within the same cost centers on their Medicare cost reports. For example, operating room supplies could be reported in an Operating Room line item or in a Medical and Surgical Supply line item. The misalignment of these costs on cost reports may be distorted further by the inaccurate matching of particular costs with departmental revenues, as different hospitals have different methods for accumulating and assigning charges. This means that there often is a mismatch between the costs and charges used by CMS to develop the national cost-to-charge ratios. The absence of coordination of these costs on cost reports becomes material under the cost-based HSRVcc proposal. In this connection, we note that, especially in the case of non-teaching hospitals – community hospitals which have no or little cost-based payments under IPPS – fiscal intermediaries have not fully audited cost reports and may only have conducted desk reviews over the past several years. The HSRVcc proposal therefore is based largely on unaudited cost data, which forms an inappropriate basis for a broad reduction of weights for surgical cases on a national basis.

Given the number of concerns regarding the HSRVcc methodology, **Y-NHH recommends the Secretary delay in moving from a charge-based system to the proposed HSRVcc system.** A delay not only would allow for an improvement in data collection, audit and application, it would provide an opportunity for the Secretary to examine areas where resource use is understated by the currently proposed HSRVcc methodology. Alternatively, Y-NHH suggest that CMS revise the rule to include a 3-year phase-in or a 3-year blend, which would apply to all hospitals except for specialty hospitals. This exception may be supported by MedPAC's finding that current charge-based weights can become biased by differential markups, which have been found to be the practice of some specialty hospitals. Given the broad spectrum of services they provide, it would be difficult for full-service hospitals, such as Y-NHH, to engage in the type of differential markups which lead to MedPAC's findings concerning specialty hospitals. As we have stated above, this problem should not be addressed by the

imposition of cost-based HSRVcc-derived weights, which introduce cost weight compression and penalize Y-NHH and similarly-situated hospitals.

b. DRGs: Severity of Illness – Y-NHH requests that the Secretary afford hospitals a new comment opportunity after this grouper is made public.

CMS is proposing to implement, in FY 2008 if not earlier, a "consolidated severity-adjusted DRG" system (by which it means a system based on a consolidated version of the APR-DRGs designed by 3M Health Information Systems). Y-NHH ask that the Secretary make public the grouper for APR-DRGs so that it may meaningfully comment on this proposal. The DRG grouper currently used by CMS is in the public domain but the APR-DRG Grouper is not. Y-NHH believes it is essential to the public comment process that the APR-DRG grouper or any hybrid model which is proposed to be implemented by the Medicare program be made public.

2. FTE Resident Count and Documentation – Y-NHH strongly urges CMS to rescind its purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of GME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

a. Background

The preamble to the proposed rule cites medical journal clubs, classroom lectures and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent ("FTE") resident counts for all IME payments (regardless of setting), and for GME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time, is that the time is not "related to patient care." However, Y-NHH concurs with CMS' 1999 position (evident in a letter, dated September 24, 1999, from Tzvi Hefter, the Director of the Division of Acute Care, to Scott McBride of Vinson & Elkins), that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures ... and presentation of papers and research results to fellow residents, medical students, and faculty.". The activities cited in both that letter and the purported "clarification" are an integral component of the patient care activities engaged in by residents during their residency programs.

b. Residency Program Activities and Patient Care

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in GME is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

Sincerely,

James Staten
Sr. Vice President, Finance
Yale-New Haven Hospital

cc: Marna Borgstorm

120

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Aspirus Wausau Hospital is a MAGNET Hospital.

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Docket Number: CMS-1488-P

Dear Dr. McClellan:

Aspirus Wausau Hospital appreciates the opportunity to submit comments related to the proposed 2007 Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Prospective System (IPPS), released on April 12, 2006 and published in the *Federal Register* on April 25, 2006.

Aspirus Wausau Hospital (AWH) is a 250-bed acute-care, regional referral hospital, serving the needs of 500,000 people throughout 13 counties in central and northern Wisconsin. The cardiovascular program represents the largest clinical program of AWH, and the second largest of 28 comprehensive cardiovascular programs in the state of Wisconsin. We perform approximately 600 open-heart surgery, 2,000 percutaneous cardiac interventions, and 500 pacemaker and ICD implants per year. Medicare patients comprise 67% of our overall cardiovascular patient population. We are proud to have been recognized repeatedly by U.S. News & World Report, Solucient, and HealthGrades, for the high quality of our clinical outcomes. Also, as measured on the basis of average charge per discharge, we are one of the lowest cost cardiovascular providers in Wisconsin.

We appreciate the considerable effort you and your staff members have put into the development and improvement of the inpatient prospective payment system (IPPS) and specifically recognize the need to continually evolve the payment system to reflect the current landscape within the field of medical services. We further recognize the significant complexities associated with gathering accurate cost data—data that should serve as the foundation of payment systems such as the proposed IPPS.

CMS is proposing to make the most significant changes to the hospital inpatient system since the late 1980s. Through our assessment, we note two major areas of concern with the proposed IPPS. First, the proposal incorporates an estimated "cost-based" system, rather than a charge-based system for determining the payment weights for each patient category in 2007. Second, the proposal endeavors to change the method of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Proposing both changes in a single regulation, with implementation in 2007, is unprecedented.

CMS proposes to base payments on "costs". In many senses, this is a positive move and is consistent with how private insurers handle costs associated with technology. However, the primary difference between CMS's proposed methodology and the private insurers is the timing and type of cost data used. Private insurers are utilizing real-time data and are paying actual invoice costs for technology used in the care of patients. In CMS's proposal, the "cost" for a particular category of patients is but a rough approximation of costs, sufficiently rough such that substantive inaccuracies result. To calculate the cost estimates for Fiscal Year 2007 payments, CMS proposes to utilize hospital claims data from Fiscal Year 2005 and hospital cost reports from Fiscal Year 2003. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights. The use of any data from Fiscal Year 2003 fails to account for current technology costs—namely drug-eluting stents and bi-ventricular pacemakers/defibrillators, mainstays in the cardiac care landscape. As such, the estimates of cost that CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for the care of Medicare patients.

It is widely known that hospitals across the country do not use a uniform approach to mark-up strategies for technology. Higher cost technologies, such as those used in the treatment of cardiac patients, are often marked up a lower rate than lower cost items. This leads to an inappropriate reflection of cost (specifically, an underestimation) when attempting to apply derived averages.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24%, and pacemakers will be reduced 12 to 14% severely impacting these services.

These proposed reductions to cardiac services are severe and are not rooted in any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to pursue a better understanding of actual costs to treat cardiac patients, any such efforts must be made with the intention of producing accurate information.

However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be grave and may potentially limit patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). This is clearly not what CMS intends to achieve with this proposal.

As such, we respectfully request that CMS delay the implementation of any changes to cardiac services reimbursement until such time as the methodology and underlying cost data are improved to ensure truly appropriate payments.

We appreciate the opportunity to provide our commentary on the 2007 CMS IPPS proposal. We remain fully supportive of prospective payment for hospital inpatient services, and commend CMS for its ongoing efforts to ensure adequate reimbursement for all clinical services. Moreover, we recognize the extremely complex issues involved in establishing appropriate reimbursement for procedures performed in the inpatient setting. We look forward to the opportunity to work with CMS to ensure that Medicare beneficiaries have continued access to high quality, efficient, and effective cardiovascular services.

Sincerely,

Rick L. Nevers
Vice President, Cardiovascular Services

bmb
c: Jodi Bloch, Vice President, Government Relations, Wisconsin Hospital Association
U.S. Senator Russ Feingold
U.S. Senator Herb Kohl
U.S. Representative David Obey
Renee Schleicher, CAE, ACCA/AAMA Board of Directors

121

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June 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
7500 Security Blvd, Mail Stop C4-26-05
Baltimore, MD 21244-1850

Re: Hospital Inpatient Prospective Payment Systems - Proposed Rule, April 25, 2006, CMS-1488-P

It is commendable that CMS has undertaken the analysis and proposal of multiple complex changes to the Inpatient Prospective Payment System in response to the MedPAC Report to Congress on Physician-Owned Specialty Hospitals, March 2005. We support the principle of more appropriate reimbursement alignment with severity of illness, resource utilization and quality of care. The following comments are submitted for your consideration on the Final Rule for FY 2007 and FY 2008 on HSRV Weights, Severity of Illness, Outliers, Implementation and Value-Based Purchasing.

"HSRV Weights" Sec. II.C.2.

Although it is critical to adopt a process that can be updated annually, the HSRV Weight methodology as proposed does not provide enough specificity for the appropriate relative weight calculation of certain DRGs that include new and high cost medical devices, technology or treatment.

Issue #1: The proposed compression of the cost report cost centers to 10 for calculation of CCRs (cost to charge ratio), eliminates appropriate average cost calculation for services, such as arterial stent-graft placement (AAA, TAA, Coronary, Carotid, other peripheral), prosthetics or specialty imaging diagnostic and therapeutic services. Inappropriate payment may prohibit beneficiaries from receiving more effective care and slow adoption of new technology or treatments.

Recommendation #1: **Expand the number of cost centers for the calculation of CCRs by creating sub-categories.** For example, a sub-category cost center could be established for "Implants" based on the Revenue Code 278 – "Other Implants" which is currently included in the cost center "Supplies & Equipment." Other subcategories that could be established pertain to Specialty Imaging Services such as CT Scan, MRI/MRA and Nuclear Medicine that are critical diagnostic and therapeutic technologies. These could be established with matching of current cost report data and claims in the SAF file. Improvement in accuracy would be achieved in future years with CMS guidance to hospitals on refined definitions for Revenue Code 278 that would clarify any confusion with other revenue codes such as 274 – Prosthetic/Orthotic Devices.

Issue #2: Utilizing the current cost report process does not provide timely and accurate data for calculating the HSRV Weights.

Recommendation #2: **Postpone the implementation for at least one year** to provide guidance to hospitals on provision of more accurate data and to Fiscal Intermediary contractors on timely cost report review and validation.

"DRGs: Severity of Illness" Sec. II.C.3.

We support adoption of refinements to reflect severity of illness and complexity of treatment. The consolidated APR-DRG method as proposed contains several issues of concern.

Issues: In comparing FY 2006 relative weights to the proposed published cAPR-DRG weights, there are ***significant decreases and increases*** due to the severity of illness grouping methodology and exclusion for complexity of treatment thus causing payment instability. These ***extreme variations*** were determined by using the 3M™ website data input page and published relative weights in the proposed rule. ***The tables of average changes published in the Proposed Rule could be masking significant shifts that may affect patients' access to appropriate treatment and create disincentives for adoption of new technology and treatment.*** Without access to complete documentation and software for comprehensive analysis, development of recommendations to correct such extremes cannot be determined.

Recommendation: **Postpone the implementation of consolidated APR-DRGs for at least one year** to allow sufficient time to evaluate other systems, such as refinements to the current DRG system similar to the DRGs that were segmented by MCV (major cardiovascular) diagnoses or other severity DRG systems. In addition, during this period a more thorough impact analysis of the consolidated APR-DRGs can be completed. ***This will allow sufficient time to ensure any system adopted will include complexity of treatment methodology and more detailed analysis to more appropriately align payments to critical treatments.***

A comment has been submitted in a separate letter by my colleague, Don Goffena, regarding a specific example of incorrect classification for endovascular repair of an abdominal aortic aneurysm and a thoracic aortic aneurysm.

The examples in Table I (page 3), illustrate the significant shifts in relative weights of frequent procedures performed for Medicare beneficiaries with CCs, such as diabetes related conditions. The extreme variations raise concerns on the methodology for the consolidated APR-DRG classification and relative weight calculation. These changes negate prior updates that refine DRGs for major cardiovascular diagnoses and new pharmacologic stroke treatment.

TABLE I

Diagnoses & Procedures	Current FY 2006		Proposed FY 2007		Proposed Severity of Illness		Change from FY 2006	
ICD-9 Codes	**DRG**	**Relative Weight**	**DRG**	**Relative Weight**	**Consolidated APR-DRG**	**Relative Weight**		
Example #1: Vascular Bypass or PTA & Endovascular Stent-Graft for the lower extremity								
440.21, 39.29 or 39.50 & 39.90	479	1.4434	479	1.2715	234	1.5918	10.3%	
440.21 & 250.52(CCs), 39.29 or 39.50 & 39.90	554	2.0721	554	1.9483	235	2.0045		- 3.3%
440.21 & 428.0(MCV), 39.29 or 39.50 & 39.90	553	3.0957	553	2.8371	235	2.0045		-35.2%
Example #2: Endarterectomy or PTA & Stent placement in the carotid artery	***With Cerebral Infarct***							
433.11, 38.12 or 00.61 & 00.64	534	1.0201	534	0.9668	34	1.2975	27.2%	
433.11 & 250.52 or 428.0, 38.12 or 00.61 & 00.64	533	1.5767	533	1.4911	35	2.7218	72.6%	
Example #3: Endarterectomy or PTA & Stent placement in the carotid artery	***Without Cerebral Infarct***							
433.10, 38.12 or 00.61 & 00.64	534	1.0201	534	0.9668	33	0.981		-3.8%
433.10 & 250.52 or 428.0, 38.12 or 00.61 & 00.64	533	1.5767	533	1.4911	34	1.2975		-17.7%
Example #4 Injection of Thrombolytics for carotid artery occlusion								
433.11, 99.10	559	2.2473	559	2.237	56	0.7865		-65.0%
433.11 & 250.52 or 428.0, 99.10	559	2.2473	559	2.237	57	1.0195		-54.6%

"Cost-Based Weights: Outlier Threshold" Sec. II.C.4.

Issue: The proposed consolidated APR-DRGs do not include a proposed outlier methodology. Although MedPAC analysis concluded that current relative weights for certain DRGs are overstated due to the presence of outlier cases, but in Sec.IV.B.5 of the Proposed Rule it is stated that currently hospitals sustain losses on all outlier cases.

Recommendation: **A postponement of at least one year** would allow for thorough analysis and development of payment impact for outlier cases and relative weight impact in any severity of illness system.

"Implementation" Sec. II.C.6 - Conclusions

Issue: Multiple implementation plans are proposed.

Recommendation: **Postpone all changes for at least one year** to evaluate alternative severity of illness systems, HSRV and thoroughly analyze transition plan impact to providers of payment and implementation cost.

I appreciate the opportunity to submit comments on the IPPS Proposed Rule and your consideration of these recommendations.

Sincerely,

Antoinette L. Sheen

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Associate
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FLORIDA HOSPITAL ASSOCIATION
An Association of Hospitals & Health Systems

122

June 8, 2006

Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
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Attention: CMS-1488-P

Dear Dr. McClellan:

The Florida Hospital Association, on behalf of its member hospitals and health systems, appreciates the opportunity to comment on the proposed fiscal year 2007 changes to the Medicare inpatient prospective payment system (PPS) published in the April 25 *Federal Register*. The proposed rule includes the most significant changes to the inpatient system since its implementation in FY1984.

The proposed rule includes numerous provisions and, as requested, comments are provided based upon CMS-designated issue categories.

DRG Weights

In the proposed rule, CMS has created a form of cost-based weights for FY2007 to move from the current charge-based weights assigned to the various diagnosis related groups. In addition, CMS has proposed implementation of consolidated severity-adjusted DRGs for FY2008 (if not earlier). In reviewing these proposed changes, it becomes apparent that such significant changes coming two years in a row result in dramatic swings in hospital reimbursement over the next few years. The redistributive impact of both proposals shifts from year to year. Such shifts in reimbursement make it difficult to manage in an efficient manner.

In support of the comments submitted by the American Hospital Association, we urge CMS to move to a simultaneous adoption of any changes to the DRG weights and classification methodology. Simultaneous implementation will provide better predictability and smooth the volatility created by these two, generally off-setting changes.

In addition, we also support a delay in the implementation of these changes for one year. This would allow time for detailed review and analysis of the weighting and classification methodology. Such a delay would also provide an opportunity for:

- Analysis of the new classification system on post-acute transfers;
- Analysis of the impact of the new classification system on the fixed-loss outlier threshold;

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- Adoption of the new classification methodology for assigning DRGs under both the long-term acute care (LTCH) PPS and the inpatient psychiatric facility (IPF) PPS – an action that would eliminate the need for some hospitals to maintain multiple GROUPERS;
- Other payers that utilize the Medicare DRG methodology to adopt the revised classification system, allowing even more hospitals to entertain a single GROUPER;
- Expansion of the number of ICD-9-CM diagnosis codes reviewed and used by CMS in assigning the consolidated severity-adjusted DRGs; and
- Release of the proposed DRG GRouper into the public domain to allow providers and others to better understand the hows and whys of the classification system.

Finally, in implementing the consolidated severity-adjusted DRGs, we urge CMS to protect one of the most basic premises of data normalization – begin the DRG codes with 1001 rather than reusing existing codes with totally unrelated descriptors.

Unadjusted Wage Index

Recently the Connecticut Hospital Association asked Baker Healthcare Consulting, Inc. (BHC) to perform an analysis of the impact of excluding the approximately 1,200 Critical Access Hospitals (CAHs) from the wage index file. The results of this analysis indicated that the National Average Hourly Wage for FY2007 is overstated by .707% since these small lower-paying hospitals have been deleted from the wage index file. This results in an understatement of the various wage indexes throughout the country. Based on the analysis presented to CMS by the Connecticut Hospital Association, Medicare payment to inpatient PPS hospitals will be understated by approximately $499,000,000 for FY2007 because of the removal of the CAH data. The BHC analysis further indicates that for FY2003-2006, Medicare payment was understated by $1.021 billion.

We believe CMS should apply a positive budget neutrality adjustment in FY2007 to compensate for the underpayments. Without the adjustment, the understatement increases each year as more hospitals become CAHs and more data are eliminated from the wage index data.

Hospital Quality Data

In order to receive a full market basket update for FY2007, the proposed rule indicates that hospitals would have to submit data for patients discharged on or after January 1, 2006, in 21 quality measures – an increase from the current 10 measures – currently part of the Hospital Quality Alliance's (HQA) public reporting. Such a retrospective data collection would require hospitals to reopen files from which data on 10 measures have already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit to the clinical data warehouse.

Rather than impose such a process on hospitals, we encourage CMS to require submission related to the expanded quality measures for patients discharged on or after July 1, rather than January 1.

EMTALA

CMS proposes to redefine "labor" under the Emergency Medical Treatment and Active Labor Act to allow a certified nurse-midwife or other qualified medical personnel operating under their scope of practice, as defined in hospital medical staff bylaws and in state law, to "certify" that a woman is in false labor. In support of the EMTALA Technical Advisory Group, "certifies" should be changed to "determines and documents."

Value Based Purchasing

We recognize the significant additional costs that are incurred when patients develop an infection and understand CMS's approach to not reward bad outcomes. However, it will be important that systems and guidance are in place for hospitals to report whether the infection was present on admission. Additionally, CMS must not penalize hospitals for caring for patients who are at a higher risk for developing an infection due to other underlying health conditions or any circumstances that might increase the likelihood of infections, such as a major trauma. The list of conditions for which infections should be avoidable should be developed and payment limited only for these conditions.

Outlier Threshold

CMS proposes a slight increase in the fixed-loss outlier threshold, from $23,600 to $25,530. Based on an AHA analysis, it does not appear that this threshold will allow expenditure of the 5.1 percent of funds withheld to fund the outlier payments. Under the methodology developed by AHA, a fixed-loss threshold of $24,000 would better achieve expenditure of the 5.1 percent outlier pool.

Again, the FHA appreciates the opportunity to comment on the proposed rule. If there are any questions on the comments provided, please do not hesitate to contact me at (407) 841-6230 or kathyr@fha.org.

Sincerely,

Kathy Reep
Vice President/Financial Services

123

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ALLINA.
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June 9, 2006

Mark McClellan, MD, PhD
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Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule. (Vol. 71 No.79 Federal Register, April 25, 2006)

Dear Dr. McClellan;

On behalf of Allina Hospitals & Clinics (Allina), I appreciate the opportunity to comment on the proposed changes identified in the 2007 Proposed Inpatient Prospective Payment Rule. Allina is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. We provide a continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, to medical transportation, pharmacy, durable medical equipment, home care and hospice services. Allina serves communities around Minnesota and in western Wisconsin. Allina hospitals submitted well over 276,000 claims in 2005, representing $1.8 billion total charges. Needless to say, we have a vital interest in the changes proposed in the Inpatient Prospective Payment Rule.

This rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, among other policies.

We recognize your efforts to support providers, suppliers and beneficiaries with this proposed payment structure. However, we have grave concerns about the pace of change CMS has proposed and are impaired in completing a rigorous analysis of specific organizational impact due to numerous issues with the limited data presented and the lack of detail to review specifically how the APR-DRGs and Consolidated Severity (CS)-DRGs support the conclusions made by CMS.

We are concerned that CMS has not taken into account all of the recommendations and methodologies of MedPAC in the resulting overhaul of the DRG system and also that CMS continues to project the expectation of payment reform and enhancements without creating and providing the underlying data, in detail, to support their conclusions. It is imperative that these changes be analyzed and reviewed for greater clarity to ensure that the resulting actions are both accurate and reasonably necessary to bring

the intended payment system reforms. This review demands more time and requires that implementation be postponed for at least one year to assure data accuracy and integrity.

Our major recommendations are included below with further discussion of our key points in the text that follows.

- **Minimum of One-year Delay:** Allina supports a minimum of a one-year delay in the proposed DRG changes given the serious concerns we have with the HSRVcc and Consolidated Severity-DRG methodology.
- **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS's proposed HSRVcc method is flawed.
- **Simultaneous Adoption of Any Changes to Weights and Classifications:** A new severity adjusted classification system should be implemented simultaneously with a new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.
- **Broader testing of the Severity Adjusted Classification System:** Additional analysis must be performed and made available to the public so that consistent understanding is gained regarding the variation within DRGs and the alternative classification system structures that could address that variation before selecting or advancing a new model. The interplay of major systems and implications for systems integrity must be tested more broadly to guarantee a smooth transition to a more complex structure.
- **Three-year Transition:** Given the magnitude of payment redistribution across DRGs and hospitals, any changes should be implemented with a three-year transition to diminish the effect of payment reductions in any single year and to support effective implementation.

HSRV Weights

Allina supports MedPAC's recommendation to move to a cost-based relative-weight methodology based on an individual hospital's claims and cost data for the purpose of weighting DRGs. However, we strongly oppose the methodology that is being proposed and believe that it is fatally flawed for the following reasons:

Data Integrity

The data is not based on hospital-specific cost but rather a national geometric mean ratio. In order to determine a hospital-specific cost each hospital's PS&R crosswalk, which is submitted with the filed cost report as an attachment to the CMS 339 form, would need to be used. The proposed formula derives a national average charge based on all hospitals being weighted equally. This affects hospitals that have historically been low charge states, such as Minnesota, negatively and allows a small rural hospital to carry the same weight as a large, urban hospital.

The data that is being used is out-dated and does not include the cost of new technology that is commonly used today, such as the drug eluting stents. In order to accurately determine the DRG weights and reimbursements these costs need to be included in any analysis that is being performed.

CMS is omitting in excess of 25% of the costs from "high cost" hospitals from the cost base, while leaving in all of the charges from those same "high cost" hospitals and assigning a relative value on reduced costs. Since the costs are being excluded, but not the charges, there is a corresponding mismatching of revenues and costs.

The data contains only audited data. Hospitals that have not been audited would not be included in the data.

The cost of organ acquisitions was included in a number of transplant DRGs resulting in the DRG weights to be incorrect. This needs to be corrected prior to implementation.

Cost Centers

CMS aggregates charges into 10 cost centers for each DRG, then applies a national cost-center level CCR (derived from the cost reports) to charge figures (from claims data). But because hospitals often report charges on the cost reports differently than charges on the claims, the cost-center level CCRs are calculated based upon a different set of charges than the charges to which the CCRs are later applied. For example, revenue code 480 Cardiology could be reported on cost report line 53 EKG or as a subscript to line 37 if the hospital has a Cardiac Cath Lab.

Therefore, it is impossible to make assumptions related to revenue codes across all hospitals without the assistance of the PS&R crosswalk. We believe this may materially distort the DRG weights and needs to be thoughtfully considered and accounted for in any methodology. If CMS is going to move to cost-based weights, regardless of the methodology, hospitals will need time to align their mapping of cost centers into departments or cost categories for purposes of cost reporting with that of claims reporting.

CMS has provided no detailed analysis to validate that the proposed changes result in better payment policy. While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone indicates the need for further analysis and study. CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the resulting data and reports. CMS should strive for creating a system that improves payments based on data that does not include the obvious flaws listed above.

DRG: Severity of Illness

There are a number of options being proposed for implementation of the HSRVcc methodology and the CS-DRG system. Allina strongly recommends that CMS implement an accurate hospital-specific costing methodology and a severity-adjusted DRG system simultaneously. However, the implementation should be delayed at <u>least</u> one year. The current sixty day implementation period would be extremely burdensome for hospitals to facilitate any of the necessary systems changes.

Integrity of Systems

We recommend that prior to implementation there should be a testing period to guarantee systems integrity. As a test site for APC implementation, we understand the significant value of testing on a small scale. We were able to identify a number of systemic issues that further delayed implementation until August 1, 2000. Additionally, there are a number of major system changes that are scheduled to be implemented in the coming years, such as the UB-04 claim form and ICD-10 coding. Couple these major system stressors with the implementation of an electronic medical record system and we could see systems stretched so tightly that we experience chaos.

It is imperative that CMS assess the impact of implementing the HSRVcc methodology and a severity-adjusted DRG system not only in terms of cost/benefit but in conjunction with the UB-04 claim form and ICD-10 coding.

Implementing ICD-10

We agree with CMS's assessment in the May 9, 2002 hospital inpatient PPS notice of proposed rulemaking that ICD-10 is an improvement over ICD-9-CM and will provide greater specificity and detail. We believe that CMS should continue with plans to implement ICD-10 while establishing a timeframe that respects the systems limitations and complexity of such a change. Implementing the significant DRG changes is a temporary fix, and a more refined DRG system can only be accomplished with more specific clinical classification systems, capable of painting a more complete picture of a patient's condition and the services provided to treat that condition – namely ICD-10-CM and ICD-10-PCS.

Contractor Changes

We are unclear to how this could affect the implementation of the MACs. Has CMS considered the implications that a drastic change in the DRG system could have on the upcoming formation of the MACs and the multiple FI/Provider changes that could occur?

Proprietary Software

The proprietary nature of the current APR-DRG and the proposed CS-DRG GROUPER is of concern. The current DRG GROUPER logic has been in the public domain since the inception of the PPS. The current 3M product is a proprietary product and not available in the public domain for hospitals or our software vendors who develop and support our patient accounting billing and case management software. Currently, we do not have any access to the underlying codes, conditions and edits utilized by 3M with its product and as a result we can not accurately comment on the interaction between severity and complexity associated with individual claims in contrast to resource consumption. Although hospitals are not required to have a grouper, hospitals that hold compliance as a top priority rely on a grouper/encoder to ensure that claims meet all edits prior to submission. Any modifications to the DRG system should be non-proprietary.

In addition, we are concerned that CMS's GROUPER does not use all diagnoses and procedures that affect a patient's severity of illness and/or the resources utilized. The current DRG GROUPER only considers nine diagnoses and up to six procedures. Allina hospitals submit electronic claims in the HIPAA compliant electronic transaction 837i standard format that allows up to 25 diagnoses and 25 procedures. However, our fiscal intermediary (FI) does not store or record these additional fields since they are not necessary to group claims under the current DRG system. These data elements have been provided to the FI and subsequently edited (deleted) out of the system. We question the validity of CMS's perception that up-coding may become an issue and therefore stop gaps need to be installed. How will we validate that the severity is real and not just a perception when the data is deleted from the current system from the FI?

Capturing all diagnoses and procedures meeting the definitions of reportable secondary diagnoses and procedures will provide a more complete picture of patient complexity. As CMS considers methodologies for refining the severity of illness system, the number of secondary diagnoses will be an important factor in determining differences in patient characteristics. This is particularly true of patients with many chronic illnesses that add to the complexity of treating them.

Transition

We recommend that CMS provide a three-year transition with a blend of the old DRG weights and the new DRG weights. The changes to DRG weights and the addition of the consolidated severity adjusted DRGs. In the first year; hospitals could be paid based on an average of DRG weights: 75 percent of the old weights; 25 percent of the new weights. The second year would be 50 percent of each, and the third year would be 25 percent of the old weights and 75 percent of the new weights. Another method of transition is dampening the reduction for DRGs with significant decrease in relative weights similar to the dampening of APC weights in the outpatient PPS. This approach could be more feasible – especially if a significant change to the classification system is made – because it does not require CMS to calculate payments using two different systems.

We further believe that a stop loss should be instituted as part of this transition. This would be similar to the approach currently used under the inpatient psychiatric PPS whereby no hospital can receive less than 70 percent of what they would otherwise have been paid under the old system. In combination with the DRG blend or dampening, this would result in less significant losses in the first year than in the last year of the transition. To avoid having to run all claims under both DRG weights, CMS could establish a payment-to-cost ratio for each hospital in FY 2006 and use that as a base against which to compare payments under the new system.

Cost-Based Weights: Outlier Threshold

Although CMS does not have the authority to change the outlier policy under current law, it does not preclude the review of multiple options such as a DRG specific outliers or day outliers. Allina recommends that CMS review these options as viable alternatives if a severity-adjusted DRG system is implemented.

Occupational Mix Adjustment

As CMS moves forward with evaluating a severity-adjusted DRG system, we would ask that the necessity of the occupational mix adjustment be reviewed. The purpose of the occupational mix adjustment was to ensure that hospitals were not paid for the additional resources needed for certain procedures in both the wage index and the resource-based DRG system. We do not believe that the occupational mix adjustment necessary if a robust severity-adjusted DRG system is implemented.

Operating Payment Rates

The rule proposes establishing a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including indirect medical education (IME), disproportionate share hospital (DSH), and new technology payments, plus $25,530. While this is not a particularly sizable increase from the FY 2006 payment threshold of $23,600; however, we remain very concerned that the threshold is already too high and should be lowered. CMS spent only 3.8 percent or $1.15 billion less than the amount set aside in FY 2005, and only 3.5 percent or $1.3 billion less than the funds withheld in 2004.

It is very disconcerting that CMS continues to increase the outlier threshold when it is evident that these funds are not being fully utilized at the current thresholds. This takes money out of the system that hospitals will never recoup unless they qualify for the ever increasing threshold. Outliers are necessary payments to cover the cost of providing essential care to high-cost patients. We recommend that CMS hold the threshold at the current level.

Hospital Quality Data

The Deficit Reduction Act of 2005 (DRA) expands quality reporting requirements for hospitals to be eligible to receive a full market basket update. The proposed rule states that to qualify for their full market basket update, hospitals would have to pledge to submit data on all 21 measures currently part of the Hospital Quality Alliance's (HQA) public reporting for patients discharged on or after January 1. Hospitals failing to submit data for the first calendar quarter of 2006 by August 15 would receive an inpatient update equal to the market basket minus two percentage points. Hospitals that fail data validation tests for data submitted for the first three calendar quarters of 2005 would also lose the two percentage points from the market basket update.

Retrospective Data Collection

Allina fully supports the HQA's effort to make more information on hospital quality available to the public, and we join with CMS in wanting to make it happen quickly and accurately. However, as written, the proposed rule would require hospitals to reopen files from which data has already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door for the introduction of many new kinds of errors in the data. To require this reopening of the files makes no sense.

We strongly urge CMS to make the data collection prospective. We do not support retrospective data collection.

Development of New Measures

When there is interest in expanding the set of measures, CMS should consider publishing the proposal at least one full year prior to the start of the fiscal year. This will enable hospitals and their vendors to put the needed data collection processes in place to be able to provide the requested data. Additionally, we ask CMS to select measures only from those used by the HQA for public reporting. To choose different measures would be counter to the desire to streamline quality reporting, and would dilute efforts to create a single source to share solid reliable information with the public.

Data Integrity

In order to assure integrity of quality data, Allina supports a data validation process. However, in the first three calendar quarters of 2005, we understand that the validation process did not have sufficient integrity to warrant hospital payments being withheld. At this juncture, we firmly believe that the problems with the validation process itself need to be resolved before any payment decisions are made solely on the basis of the contractor's work. We strongly urge CMS to review, on a case-by-case basis, any incidence where a hospital's payment would be put in jeopardy as a result of the validation process. It should allow the hospital to submit information showing that it made a good-faith effort to supply the data warehouse with accurate information so that the public could be informed about the quality of its care. If the hospital has made a good-faith effort, it should receive full payment regardless of whether the data are deemed accurate enough for public display. In addition, CMS should instruct its QIO data warehouse to accept any significant corrections so that the public can have a full and accurate picture of hospital quality.

New Technology

Section 503 of the MMA provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. However, CMS continues to withhold approval of new technologies and considers only a few technologies a year for add-on payments.

We are concerned about CMS's ability to implement add-on payments for new services and technologies in the near future. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. We are experiencing significant challenges with coding of new technology, for example, carotid stents. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading. Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to as ICD-10) were developed as replacement classification systems. CMS should work toward implementation of ICD-10 as a necessary component for implementation of severity-adjusted DRGs and as a means to handle codes required to support billing for new technology.

EMTALA

Allina supports CMS's proposal to modify the definition of "labor" at 489.24(b) to allow a certified nurse-midwife or other qualified medical personnel operating under their scope of practice, as defined in hospital medical staff bylaws and in state law, to certify that a woman is in false labor. This change recognizes that licensure and scope of practice should remain under the purview of state law and regulation. Further, this change provides hospitals with the staffing flexibility needed to maintain access to and the efficiency of vital obstetrical services, particularly in rural hospitals.

Under the proposed rule, a hospital with "specialized capability" is required to accept appropriate transfers under EMTALA regardless of whether it has a dedicated ED. Guidance is still needed on the definition of specialized capability.

Hospital Acquired Infections

In the proposed rule, CMS has asked for ideas about how to effectively implement the DRA provision requiring the agency to identify instances in which the reliable application of science and appropriate processes of care should prevent infections, and to ensure that Medicare does not pay more for the hospital care of patients who becomes infected as a result of their care than it does for patients who are infection free.

We have significant issues with the suggestion that if an infection is not noted as "present on admission" that the infection is hospital acquired and therefore we should not be paid for treating the patient complications. It is difficult to pinpoint the cause of an infection, especially one that develops shortly after admission but was not indicated on admission. A recent article in Infection Control & Hospital Epidemiology (Sherman, April 2006) entitled, *"Administrative Data Fail to Accurately Identify Cases of Health Care-Associated Infection,"* notes that "no standardized method for using claims data to find cases of health care acquired infection has been validated." We are deeply concerned that CMS would implement a payment methodology tied to administrative data alone when we are clear that this data alone does not present a valid indication of cause. Using coding data for "present on admission" would result in a significant number of infections deemed as "hospital-acquired" when they may not be, thus leading to CMS non-payment for legitimate complications. We suggest that this issue be approached from a quality standpoint rather than from a cost savings perspective and that administrative data is not utilized as the only factor to accurately identify a hospital acquired infection.

We can support CMS in building upon the substantial work underway in the Surgical Care Improvement Project (SCIP). Surgical wound infections are among the most common and hazardous hospital-acquired infections. The existing expert SCIP group can help identify a few surgical procedures that might be most appropriate for this initiative. We believe these are likely to be relatively "clean" surgeries, meaning surgeries on patients whose conditions or wounds have not already put them at higher risk for infection, and patients who do not already have a variety of complicating conditions that would place them in higher paying DRGs. Additional expertise on coding and the DRG GROUPER is also needed for these discussions to help address questions of what data are helpful and readily available to determine which infections were acquired in the hospital versus the community, and which codes actually lead to enhanced payments.

In addition, there is good evidence to suggest that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. Therefore, we suggest that by utilizing the SCIP program as the basis for responding to the congressional mandate, CMS could choose not to penalize a hospital if, despite their best efforts, an infection occurs. For example, if a hospital's performance on the SCIP surgical wound infection prevention measures show that it reliably performs the necessary infection prevention steps all or nearly all of the time, CMS might not make any change to the current payment system for that hospital.

Transparency of Health Care Information

The proposed rule includes the introduction of a proposed initiative to expand the public availability of consumer information on health care quality and pricing. HHS intends to identify several regions in the United States with high health care costs where there is significant interest in reducing those costs and improving health care quality.

A good foundation is being developed for access to data quality. Through the voluntary reporting of the current 10 measures, the expansion to the 21 measures for 2007, and access to the *Hospital Compare* Web site, consumers are able to get a high level look at the quality indicators for selected hospitals. We support ongoing efforts to further expand public availability of hospital quality information so long as the infrastructure supports consistency and data integrity.

We have a good start on the quality data transparency; however, pricing transparency creates significant challenges. We firmly believe that people deserve meaningful information about the price of their hospital care and we are committed to sharing information that will help people make important decisions. Sharing pricing information, however, is more challenging because hospital care is unique. Hospital prices can vary based on patient needs and the services they use; prices reflect the added costs of hospitals' public services role – serving the essential health care needs of a community 24 hours a day, seven days a week.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge. We support the following objectives for improving pricing transparency:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;

- Explaining to consumers how and why the price of their care can vary; and
- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

In the proposed rule CMS presented a number of options, we request that CMS consider the objectives as noted above and work to build a model for price reporting and vehicles for access that provide consumers across the country the same access to the same information so they are able to make effective comparisons on both quality and price. With all of the various approaches being mandated and implemented at the state level across the country, we fear that we will never get a consistent, meaningful model for reporting.

Allina does not support using the conditions of participation as a means to mandate and monitor price transparency.

In closing, I would again thank CMS for the opportunity to respond to the proposed rule. The gravity of these changes will create significant financial implications, of which we cannot assess due to the lack of a solid data foundation utilized in building the proposed modifications to the core components of the IPPS program. With an inability to determine the real impact of these changes, we are ill prepared to implement the final rule within the established 60-day timeframe. We again urge CMS to delay implementation of the changes to DRG weights and severity adjusted DRGs. There is so much more to learn through a comprehensive testing approach than to rely on the small sample of independent review that has been done with the limited resources available to this point.

Additionally, we are concerned about the ability of all of the non-government payers who follow the current DRG structure to make necessary adjustments to their systems and processes in the 60-day timeframe between the publishing of a final rule and the implementation date.

If you have any questions regarding these remarks, please feel free to contact me at 612-262-4912.

Sincerely,

Nancy G. Payne, RN
Director Regulatory Affairs

Minnesota Chapter
P.O. Box 24732
Minneapolis, MN 55424-0732

June 1, 2006

Mark McClellan, MD, PhD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mailstop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule. (Vol. 71 No.79 Federal Register, April 25, 2006)

Dear Dr. McClellan:

On behalf of the Regulatory Committee of the Minnesota Chapter of the Healthcare Financial Management Association, we appreciate the opportunity to respond to your 2007 Proposed Inpatient Prospective Payment System (IPPS) rule that was published in the Federal Register on April 25, 2006. In response to the proposed rule, we offer the following comments.

We are concerned that CMS has not taken into account all of the recommendations and methodologies of MedPAC in the resulting overhaul of the DRG system and that CMS continues to project the expectation of payment reform and enhancements without creating and providing the underlying data to support their conclusion. The tables presented are based on MedPAC data and analysis based on incorporating all of its recommendations and methodologies. CMS is proposing the most drastic changes to the DRG system since its implementation in 1983. It is imperative that these changes be reviewed with greater clarity to insure that the resulting actions are in fact what were intended. This also requires that implementation be postponed for at least one year to ensure underlying data accuracy and integrity

HSRV Weights

The Regulatory Committee supports MedPAC's recommendation to move to a cost based relative weight methodology based on claims data for the purpose of weighting DRGs.

However, we strongly oppose the methodology that is being proposed and believe that it is flawed for the following reasons:

- The data is not based on a provider's hospital specific cost ratio, which is what was intended by MedPAC's recommendation, but rather a national geometric mean ratio. In order to determine a hospital's specific cost each hospital's charges must be matched with a PS&R crosswalk. The PS&R crosswalk is submitted with the as filed cost report as an integral attachment to the CMS 339 form. The proposed formula derives a national HSRVcc based on all hospitals being weighted equally, which allows a small rural hospital to carry the same weight as a large, urban hospital.
- There are only 10 categories being identified, which dilute the accuracy of the data and cannot capture the true cost of specialty service lines. Additionally, each hospital may chose to report revenue codes differently depending on where the cost is reported on the cost report. For example, revenue code 480 Cardiology could be reported on cost report line 53 EKG or as a subscript to line 37 if the hospital has a Cardiac Cath Lab. Therefore, it is impossible to make assumptions related to revenue codes across all hospitals without the assistance of the PS&R crosswalk.
- The data that is being used is out-dated and does not include the cost of new technology that is commonly used today, such as the drug eluding stents. In order to accurately determine the DRG weights and reimbursements these costs need to be included in any analysis that is being performed
- CMS is omitting 25% of the costs from "high cost" hospitals from the cost base, while leaving in all of the charges from those same "high cost" hospitals. Since the costs are being excluded but not the charges there is a mismatching of revenue and cost.
- The data contains only audited data. Hospitals that have not been audited would not be included in the data.
- The cost of organ acquisitions was included in a number of transplant DRGs causing the DRG weights to be incorrect. This needs to be corrected prior to implementation.

Given the opportunity to rebase the DRG system, CMS should strive for creating a system that improves payments based on data that does not include the obvious flaws listed above. This should be done immediately and hospitals should be allowed to comment on the corrected data. As a result, any implementation would need to be delayed at <u>least</u> one year.

<u>DRG: Severity of Illness</u>

There are a number of options being proposed for implementation of the HSRVcc methodology and the severity-adjusted DRG system. The Regulatory Committee strongly recommends that any changes to the DRG weights and classifications be implemented simultaneously. However, the implementation should be delayed at <u>least</u> one year and alternative methodologies should be considered. The current sixty day implementation period would be extremely burdensome for hospitals to facilitate. CMS

needs to extend the comment period to allow hospitals the time needed to evaluate the effects of such drastic changes; particularly since they span multiple years.

It is our recommendation that prior to implementation CMS should consider multiple options for rebasing the DRG system, rather than just the one option being proposed. In the proposed rule, CMS is soliciting the provider community to comment on other alternatives. Once these alternatives are presented to CMS, hospitals should have a second comment period to review all of the alternatives presented as the result of the proposed rule. Secondly, with the implementation of any system change this dramatic there should be a testing period to ensure system integrity. During the implementation of APC's, the testing period identified a number of systemic issues that further delayed implementation until August 1, 2000. Further, there are a number of system changes that are scheduled to be implemented in the coming years, such as the UB04 claim form and ICD 10 coding, in addition to the implementation of an electronic medical record system at a number of hospitals. We encourage CMS to review the cost benefit of implementing the HSRVcc methodology and a severity-adjusted DRG system in conjunction with the UB04 claim form and ICD 10 coding to help alleviate the additional cost of multiple system upgrades both for the hospital and the Fiscal Intermediaries.

It is also unclear to us how this could affect the implementation of the MACs. Has CMS considered the implications that a drastic change in the DRG system could have on the upcoming formation of the MACs and the multiple FI/Provider changes that could occur?

Finally, the current 3M product is a proprietary product and not available in the public domain by hospitals or our software vendors who develop and support our patient accounting billing and case management software. Currently we do not have any access to the underlying codes, conditions and edits utilized by 3M with its product as a result we can not accurately comment on the interaction between severity and complexity associated with individual claims and any correlation with resource assumption. Although hospitals are not required to have a grouper, hospitals that hold compliance as a top priority rely on a grouper/end coder to ensure that claims meet all edits prior to submission. Any modifications to the DRG system should be non-proprietary.

Cost Based Weights: Outlier Threshold

Although CMS does not have the authority to change the outlier policy under current law, it does not preclude the review of multiple options such as a DRG specific outliers or day outliers. The Regulatory Committee recommends that CMS review these options as viable alternatives if a severity-adjusted DRG system is implemented.

Occupational Mix Adjustment

As CMS moves forward with evaluating a severity-adjusted DRG system, we would ask that the necessity of the occupational mix adjustment be reviewed. The purpose of the occupational mix adjustment was to ensure that hospitals were not paid for the additional resources needed for certain procedures in both the wage index and the resource based DRG system. Is the occupational mix adjustment necessary if a severity-adjusted DRG system is implemented?

Wage Data

A basic review of the wage index data revealed that a number of hospital's wage data was outside three standard deviations in areas such as benefits as a percent of salaries, contract labor hourly rates, and home office hourly rates. This data should be reviewed further to determine whether it is reasonable and should be included in the wage index calculation. *Please see the attached analysis.*

GME Payments

Our concern is that several types of graduate medical education activities are being changed from patient care activities to solely direct medical education activities not as a clarification, but as a new regulation. For example, "Morning Report" is a meeting that most accredited graduate medical education (GME) programs have every day. The purpose of the meeting is to manage patient care activities for the residents for the day and include infection control and quality assurance activities that have been deemed patient care related activities for all other hospital personnel since the establishment of 42 CFR 413.9. Another "conference" that is a regular part of many GME programs is the Morbidity and Mortality conference which is a quality assurance conference held at the hospital dealing specifically with quality assurance of the resident's clinical practice. These are only two of several "conferences" that are being misconstrued as didactic when they are specifically patient care related.

During the per resident amount (PRA) audits for several of the hospitals in the Twin Cities, independent research activity rotations (i.e. counted for FTE purposes) were included in the direct medical education FTEs used to determine the hospital specific per resident amounts. This independent research is a standard allowable elective rotation within an ACGME certified program. Much of the research may happen at the hospital's medical library. Much of the research may happen at home at the resident's study desk. All of it has been included in the FTEs used to calculate the PRA amount. The assumption made for PRA setting was that the activities were includable. Now we have a clarification (new regulation) that states they are not includable. If this is a clarification (new regulation) and we have a change of accounting method, we should consider a change in the PRA amount for the hospitals that exclude these newly excluded FTE amounts.

Operating Payment Rates

Outliers are necessary payments to cover the cost of providing necessary care to high-cost patients. In the proposed rule there is data to support that in both 2005 and in 2006 CMS paid out less what was set aside for outlier payments. It is concerning that CMS continues to increase the outlier threshold when it is evident that these funds are not being fully utilized at the current thresholds.

Thank you for your considerations of our comments. If you have any questions related to these comments, I can be reached at (612) 262-4721.

Sincerely,

Lissa Benson

Lissa Benson
Co-chair Regulatory Committee

Attachment

Attachment A

PROV	provname	benes to salary %	[redacted]	home off $/hr
140150	UIC MEDICAL CENTER	0.9219		
190199	VILLA FELICIANA	0.4818		
230065	ST. JOHN NORTHEAST COMMUNITY HOSP	0.4638		
510077		0.4636		
180069		0.4593		
050145	COMMUNITY HOSP. MONTEREY PENINSULA	0.4528		
240019		0.4374		
360096	E. LIVERPOOL CITY HOSPITAL	0.4370		
230222	MIDMICHIGAN MEDICAL CTR	0.4305		
180050		0.4298		
050546	PORTERVILLE DEVELOPMENTAL CENTER	0.4232		
240010		0.4170		
330403	MONROE COMMUNITY HOSPITAL	0.4145		
010108	PRATTVILLE BAPTIST HOSPITAL		234.27	
370083	PUSHMATAHA HOSPITAL		217.89	
110100	JEFFERSON HOSPITAL		210.08	
010100	THOMAS HOSPITAL		178.99	
450754			170.66	
050714	SUTTER MATERNITY & SURGERY CENTER		163.64	
450188			160.86	
010001	SOUTHEAST ALABAMA MEDICAL CENTER		158.84	
350003			143.38	
190184	CITIZENS MEDICAL CENTER		141.73	
180035			141.22	
370015	MAYES COUNTY MEDICAL CENTER		139.36	
010110	BULLOCK COUNTY HOSPITAL		135.98	
260015			134.25	
370084	HASKELL COUNTY HOSPITAL		133.78	
240056			131.73	
390058			129.43	
450102				413.04
510007	ST. MARY'S MEDICAL CENTER, INC.			214.28
510071	BLUEFIELD REGIONAL MEDICAL CENTER			186.24
110190	FLINT RIVER COMMUNITY HOSPITAL			182.24
140213	SILVER CROSS HOSPITAL			177.08
140091	CARLE FOUNDATION HOSPITAL			170.00
050039	ENLOE MEDICAL CENTER			164.67
510053	ST. JOSEPH'S HOSPITAL			157.24
330394	UNITED HEALTH SERVICES HOSPITALS			153.24
170006				151.34
320001				146.78
140063	OAK PARK HOSPITAL			139.97
390115	FRANKFORD HOSPITAL			139.49
050502	ST. VINCENT MEDICAL CENTER			136.06
050104	ST. FRANCIS MEDICAL CENTER			136.06
050420	ROBERT F. KENNEDY			136.06
090001				130.01
	mean	**0.2480**	**50.35**	**49.22**
	standard deviation	**0.0542**	**25.42**	**25.56**

125

C. R. Bard, Inc.
730 Central Avenue
Murray Hill, NJ 07974

BARD

June 9, 2006

The Honorable Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: *CMS-1488-P: Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Calendar Year 2007 Rates*

Dear Dr. McClellan:

On behalf of C. R. Bard, Inc., I am pleased to offer the following comments on the April 25, 2006 proposed rule for the Medicare hospital inpatient prospective payment system (*Federal Register*, Vol. 71, No. 79). This rule proposes a number of significant refinements to the diagnosis-related group (DRG) system.

One of the key payment refinements addressed in the proposed rule is a quality adjustment in DRG payments for certain conditions, including hospital-acquired infections, that were not present on hospital admission. This payment adjustment, a requirement of section 5001(c) of the *Deficit Reduction Act of 2005*, is scheduled to become effective for Medicare payments made in FY 2008. Bard's comments relate to this quality adjustment.

For more than 95 years, C. R. Bard, Inc. has committed its resources to creating innovative products and services that meet the needs of healthcare providers and patients. Today, Bard is a leading multinational developer, manufacturer, and marketer of innovative, life-enhancing medical technologies in the fields of vascular, urology, oncology and surgical specialty products. Bard is committed to advancing the technology of diagnosis and intervention to help reduce healthcare costs and improve patient outcomes. Founded in 1907, C. R. Bard has facilities in eight U. S. locations and in 20 other countries around the world, and employs more than 8,100 people.

Value-Based Purchasing / Quality Adjustment for Hospital-Acquired Infections

Section 5001(c) of the *Deficit Reduction Act of 2005* (Public Law 109-171) encourages hospitals to avoid preventable complications by not allowing them to benefit from higher

payment associated with infections acquired during a hospital stay. Bard supports the emphasis Congress has placed on preventing hospital-acquired infections—and finds it long overdue.

According to the Centers for Disease Control and Infection, these conditions account for an estimated 2 million infections, 90,000 deaths, and $4.5 billion in excess health care costs annually in this country. And much of the financial burden resulting from hospital-acquired infections is borne by public programs like Medicare and Medicaid.

To focus on one state's experience, a recent study by the Pennsylvania Health Care Cost Containment Council found that there were 7.5 hospital-acquired infections per 1,000 admissions in Pennsylvania hospitals in 2004, and that Medicare and Medicaid were billed for 76 percent of the reported 11,668 hospital-acquired infections in the state. These infections led to more than 1,500 deaths, over 200,000 additional hospital days, and $2 billion in additional hospital charges. But the patient safety and financial impact of hospital-acquired infections appears to be even bigger than originally reported. During the first nine months of 2005, hospitals identified 13,711 hospital-acquired infections, compared to 11,668 for all 12 months of 2004.

Bard believes that studies, like the Pennsylvania report, have been helpful in convincing policymakers of the need for new payment approaches that reward performance. We at Bard believe that section 5001(c) will spur hospitals to take long-overdue action—in the training they provide care-givers, and in the technologies they use to reduce the rate of hospital-acquired infections.

We understand that the first step in implementing section 5001(c) is to identify by October 1, 2007, at least two high-cost or high-volume conditions (or two conditions that are both high-cost and high-volume), preventable through the application of evidence-based guidelines, that are present as a secondary diagnosis, and that result in the assignment of a case to a DRG with a higher payment rate. We encourage CMS to focus on DRGs that are differentiated based on the presence or absence of a complication or a co-morbidity (CC). There are more than 100 pairs of such DRGs, where the DRG that contains the complication or co-morbidity has the higher payment rate. We think that CMS should not pay the higher-cost DRG if a hospital-acquired infection is the reason for the complication or a co-morbidity (CC) and assignment to a higher-paying DRG.

In particular, we believe that CMS should seriously consider focusing on nosocomial infections, particularly urinary tract infections (UTIs) in response to the section 5001(c) requirement. We understand that there is a significant variation among hospitals infection rates in this area. Further, there is a literature showing that hospital staffing levels, hospital training and safety practices, and the choice of medical technology (e.g., the use of silver-alloy coated drainage catheters instead of standard urinary drainage catheters) all result in a reduction of nosocomial UTI rates.

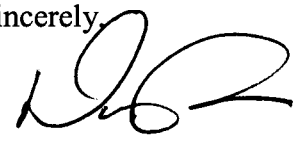
For these reasons we recommend that CMS prevent the secondary diagnosis codes for UTI (e.g., ICD-9-CM codes 599.0, *urinary tract infection*, and 996.64, *infection and*

inflammatory reaction due to indwelling urinary catheter) from being used as complications that result in the assignment of cases to higher-cost DRGs due to the presence of a complication or a co-morbidity (CC).[1] Doing this would create incentives for hospitals to take the staffing, training, and technology utilization steps needed to reduce the incidence of hospital-acquired infections.

*****

Thank you for considering these comments and recommendations. We at Bard stand ready to assist you if you have any questions. Do not hesitate to call (908-277-8170) or e-mail me (david.parr@crbard.com) at your convenience.

Sincerely,



David Parr
Vice President of Reimbursement

[1] See, for example a recent paper by Jerry Stringham and Nancy Young, "Using MedPAR Data as a Measure of Urinary Tract Infection Rates: Implications for the Medicare Inpatient DRG Payment System," *Perspectives in Health Information Management*, 2;12 (Fall, 2005).

126

Pennsylvania Hospital

University of Pennsylvania Health System

Gordon H. Baltuch, M.D., Ph.D., FRCS (C)
Assistant Professor of Neurosurgery

Penn Neurological Institute at
Pennsylvania Hospital

June 7, 2006

RE: CMS-1488-P
DRG's NEUROSTIMULATORS

To Whom It May Concern:

I am Gordon Baltuch, a neurosurgeon, at Pennsylvania Hospital. In this capacity, I have seen the profound impact that Deep Brain Stimulation (DBS) has to change the quality of life of a patient suffering from a debilitating movement disorder.

Deep Brain Stimulation is a time consuming venture and it is the most technically demanding operation that I perform as a neurosurgeon. When we do DBS surgery at our institution, it is not unusual that the success of the operation will be dependent on the efforts of 20-30 individuals that represent my team. These surgeries require hours of planning that is not currently reflected in the current reimbursement scheme. It is not unusual for a Deep Brain Simulation electrode implant surgery to take 5-8 hours of my time.

It is my opinion that unless this therapy is moved into a clinically coherent DRG which adequately reflects the cost associated with a full system Kinetra implant, financial barriers will impact our ability to provide this life changing therapy to Medicare patients that desperately need our help.

With the expiration of the New-Tech Add-On Payment, we are concerned that full-system Kinetra implants will be inadequately paid in their current DRG's, 001 and 002.

CMS acknowledged that the average charges for full-system Kinetra cases in DRG 001 are comparable to cases in DRG 543; however, they proposed no change for FY07. We encourage CMS to move full-system Kinetra cases into DRG 543 in FY07 given the similarity of resource consumption.

CMS proposed implementation of consolidated severity adjusted DRG's in FY08 or earlier. However, severity-adjusted DRG's do not account for technologies such as Kinetra. We encourage CMS to make the appropriate adjustments for innovative technologies such as Kinetra to consolidated severity-adjusted DRG's before implementing them.

Sincerely,

Gordon H. Baltuch, MD, PhD, FRCS (C)
Associate Professor of Neurosurgery

330 South Ninth Street • Philadelphia, PA 19107 • (215) 829-7144 • Fax: (215) 829-6645

UNIVERSITY OF
PENNSYLVANIA
HEALTH SYSTEM

Ralph W. Muller
Chief Executive Officer

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P
Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

Thank you for the opportunity to comment on the proposed rule (71 FR 23995-24550, April 25, 2006) for the Hospital Inpatient Prospective Payment System. The University of Pennsylvania Health System (UPHS) serves the Greater Philadelphia area through three teaching hospitals, offering a full range of acute and post-acute services. Combined, our hospitals admit over 15,000 Medicare Beneficiaries on an annual basis and provide training to over 900 interns and residents.

1. PROPOSED CHANGES TO DRG CLASSIFICATIONS AND RELATIVE WEIGHTS

We commend CMS for its efforts to modify the existing DRG payment system to make payments for inpatient hospital services equitable and fair. While we may dispute the methodology for developing the new DRG weights, we do agree that the existing system needs to be refined.

a. HSRV WEIGHTS

Cost-to-Charge Ratio Inconsistency - We believe that the methodology employed to determine the new DRG weights is inherently flawed. First, we do not dispute the use of MedPAR charge data for the purpose of grouping charges into one of the 10 Cost Center Charge Groups. The flaw that we see is when these charges are

converted to cost. There is not a consistent matching of MedPAR charges to the costs and charges taken from the HCRIS files.

For example, we informally surveyed several hospitals within the Philadelphia area and found that nearly all of our peers included Cardiac Catheterization on line 59 of the Medicare Cost Report. According to the Table on page 24009-24010, Cardiology MedPAR charges are grouped to the Cardiology Cost Center, but line 59 from the Medicare Cost Report is included in the "Other Services and Charges" Cost Center.

Applying the MedPAR charges to a cost-to-charge ratio that does not include those charges goes against all principles of matching revenues and expenses. This may help to explain why the proposed DRG weights for Cardiac DRGs experienced some of the largest declines from the existing weights. In the case of our three hospitals, the cost-to-charge ratios for Cardiac Catheterization are significantly higher than the cost-to-charge ratios for Lines 53 and 54 (EKG and EEG). Thus, the Cardiology Cost Center costs for each DRG would be understated because the Cardiac Catheterization MedPAR charges are being applied against a cost-to-charge ratio that does not include Cardiac Catheterization services.

When the Medicare Cost Report is prepared, hospitals are required to assign a four-digit CMS code that describes the nature of a sub-scripted or additional, cost report line. Below, we have reproduced the Medicare Cost Report Instructions that outline the use of the cost center code. We recommend that any matching of HCRIS data to MedPAR data should use the cost center code rather than the Medicare Cost Report Line. This will ensure proper matching of MedPAR Charges to the relevant cost-to-charge ratios.

> "Standard (i.e., preprinted) CMS line numbers and cost center descriptions cannot be changed. If you need to use additional or different cost center descriptions, add additional lines to the cost report. Where an added cost center description bears a logical relationship to a standard line description, the added label must be inserted immediately after the related standard line. The added line is identified as a numeric subscript of the immediately preceding line. For example, if two lines are added between lines 7 and 8, identify them as lines 7.01 and 7.02. If additional lines are added for general service cost centers, add corresponding columns for cost finding.
>
> Cost center coding is a methodology for standardizing the meaning of cost center labels as used by health care providers on the Medicare cost reports. Form CMS-2552-96 provides for 90 preprinted cost center descriptions on Worksheet A. In addition, a space is provided for a cost center code. The preprinted cost center labels are automatically coded by CMS approved cost reporting software. These 90 cost center descriptions are hereafter referred to as the standard cost centers. An additional 57 nonstandard cost center descriptions have been identified through analysis of frequently used labels."

Timeliness of Cost Data – The application of FY 2004 MedPAR charge data against cost-to-charge ratios calculated using FY 2003 Cost Reports does not consider the fact that many new technologies (especially drug-eluding stents and other cardiac implantable devices) were just emerging in FY 2004. Thus, the charges exist for

these items in FY 2004, but the often very high cost of these items was not present in FY 2003, which means that the DRGs utilizing these devices have costs which are understated. This may help to explain why the DRGs for Cardiac procedures seem to be experiencing the greatest decline under the proposed changes.

National Average Cost-to-Charge Ratio – We disagree with the use of the geometric mean cost-to-charge ratio for each of the 10 cost centers. Using a geometric mean without giving any weight to volumes means that the ratios of a small rural hospital will carry as much weight of a large urban teaching hospital. Furthermore, we agree with the decision to remove the cost report data for certain classifications of hospitals (IRFs, IPFs, LTCHs, etc.) and the decision to remove any ratios that were either less than 0.01 or greater than 10. However, we do not agree with the exclusion of additional data merely because it does not fit within 1.96 standard deviations from the mean.

b. DRGs: Severity of Illness

We are in agreement with the MedPAC recommendation of moving to a DRG system that more accurately reflects the variation of severity within a particular diagnosis group. However, we have several concerns with how this will be achieved. First, and foremost, is the ability of providers to model the prospective modifications. Only through great expense and effort (from obtaining detailed MedPAR data to obtaining APR-DRG grouping software from 3M) can hospitals fully understand the magnitude and the scope of what CMS has proposed. Second, we are concerned with the relative short period of time to fully model and understand the impact of such a sweeping reform of the Medicare payment system as well as the lack of any transition period to any new payment system.

While 3M did offer a web site for grouping claims into an APR-DRG, it was limited to only calculating one claim at a time. With more than 15,000 Medicare claims annually, a single claim entry process does not support the ability to provide a timely analysis of the proposed changes. Even then, the APR-DRG would have to be matched to the corresponding CSA-DRG using the crosswalk published in Appendix D of the Federal Register. This appendix was not made readily available in a usable electronic format, so the matching would have to be done manually. Once matched to the CSA-DRG, the related weight could be retrieved from the file of CSA-DRG weights that was made available on the CMS web site, but not mentioned in the Federal Register. Clearly, this represents not only an administrative, but also a financial burden to any hospital that seeks to understand the potential impact to Medicare payments.

With respect to implementation of both the HSRV cost-based DRG weights and the CSA-DRG methodology, we are strongly in favor of a transition period. Significant Medicare payment changes in the past have almost always been accompanied by some sort of transition mechanism to mitigate any large variation in payment from one year to the next. Inpatient Rehabilitation PPS, Inpatient Psychiatric PPS, Skilled

Nursing Facility PPS and Inpatient Hospital Capital PPS have all had transition periods of varying length (from 2 years to 10 years). Clearly, such a sweeping reform would warrant a transition period as well.

2. OPERATING PAYMENT RATES

a. FY 2007 Outlier Fixed-Loss Cost Threshold

Under the Medicare inpatient prospective payment system, if the costs of a particular Medicare case exceed the relevant DRG operating and capital payment (including any disproportionate share (DSH), IME, or new technology add-on payments) plus an outlier threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case's costs above the threshold calculation.

The outlier fixed-loss cost threshold is set at a level that is intended to result in outlier payments that are between five and six percent. Outlier payments are budget-neutral. Each year the Agency reduces the inpatient standardized amount by 5.1 percent and estimates a cost threshold that should result in outlier payments that equal 5.1 percent.

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus a $25,530 outlier threshold, an increase of 8.2 percent over the FFY 2006 threshold of $23,600.

CMS proposes an increase to the threshold even though the Agency estimates that outlier payments for FFY 2006 will represent only 4.71 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 4.1 percent of total DRG payments in FFY 2005 and, according to the August 12, 2005 final rule, only 3.52 percent of total DRG payments in FFY 2004 (70 Fed. Reg. 47496). Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in all three consecutive years, contrary to the intent of the outlier payment policy.

We believe the FFY 2007 cost threshold must be reduced. CMS relies only on charge inflation to determine projected increases in per case costs, which determines outlier payment outlays. Along with the American Hospital Association (AHA), and Federation of American Hospitals, the Association of American Medical Colleges (AAMC) conducted an analysis that incorporates both cost and charge inflation, which we believe makes the threshold calculation more accurate and reliable. Using this methodology, the threshold should be $24,000 for FFY 2007. We urge you to review and give serious consideration to the methodology, as described in more detail in the AHA's comment letter.

3. OTHER DECISIONS AND PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS AND GME COSTS

a. GME Payments

We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care" The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

Interns and Residents' time is often assigned in monthly, or even weekly, rotation blocks. Among the more than 50 accredited programs at our hospitals, very few of the programs share similar rotation blocks; some even differ by Program Year. For example, the Emergency Medicine residents follow a schedule that is made up of 13 blocks that each last for 28 days, while Dermatology residents utilize a schedule made up of 52 weekly periods. Training opportunities such as conferences and journal clubs are not included on the rotation schedules. When such activities are held, the resident is still responsible for answering pages and responding to emergency calls, just as they would be if they were eating breakfast, lunch, or dinner at the hospital. The exclusion of this time from IME not only doesn't make sense, but it would seem to create an undue record keeping burden on hospitals and the intermediaries that would have to audit said records.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins].

We support the Agency's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

4. PROPOSED CHANGES TO HOSPITAL WAGE INDEX

a. Occupational Mix Adjustment

Notwithstanding the recent Provider Reimbursement Review Board (PRRB) decision regarding the full implementation of the Occupational Mix Adjustment in the FY

2007 IPPS rate-setting process, we disagree with the lack of adequate notice and sufficient time to fully comply with the new reporting requirement. In past years, there was always adequate time for the submission, review and correction of wage index data. As a result, there were very few surprises when the proposed rules were published since both the provider and intermediary had more than enough time to resolve any and all errors.

Condensing the submission, review and correction period into less than 60 days has the potential to produce errors that could unfairly redistribute payments. We urge CMS to consider either delaying the implementation of the occupational mix adjustment, or to consider allowing retroactive changes to the adjustment should errors be discovered after the fact.

Thank you again for the opportunity to comment on this proposed rule. If you have questions regarding anything I have commented upon, please do not hesitate to contact me at 215-662-2203.

Sincerely,

Ralph W Muller

Ralph W. Muller

cc: Michael Leavitt, Secretary of Health and Human Services
Robert Portman, Director of Office of Management and Budget
Robert Dickler, Association of American Medical Colleges

125

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June 12, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Docket Number: CMS –1488-P

Dear Dr. McClellan:

Baptist Hospital appreciates the opportunity to submit comments related to the proposed 2007 Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Prospective Payment System (IPPS), released on April 12, 2006 and published in the *Federal Register* on April 25, 2006.

Baptist Hospital is a 492 bed tertiary care hospital, the largest in the Baptist Health Care network. Baptist Hospital provides a full range of medical, surgical, obstetrical and cardiovascular services. Specialized critical care is provided by the hospital's emergency center and three intensive care units: coronary, surgical and neurological intensive care. One of Baptist Hospital's greatest strengths is its commitment to quality and excellence. We believe, as a 2003 Malcolm Baldrige National Quality Award winner, we have demonstrated this commitment to excellence. Baptist Hospital, Inc. received the highest honor given to American businesses, the Malcolm Baldrige National Quality Award. We also demonstrate our commitment to excellence every day in the way we treat our patients and have remained in the top 1% , in the nation, in Patient Satisfaction as rated by the Press Ganey survey tool. In addition, Baptist has been named one of Fortune's Top 100 companies to work for, in the country, for the past five consecutive years. Our Cardiac program, HeartFirst, is an extensive and complete system of heart-related services provided by Baptist Health Care. Our mission is to provide the highest quality cardiac care and to prevent needless death and disability from heart disease. Baptist Hospital was named one of the nations 100 Top Cardiovascular Hospitals as part of a study featured in Modern Healthcare magazine. One of only 30 community hospitals included on the list, Baptist performed better than its peers in four areas examined by the study: mortality rates for heart attacks, congestive heart failure and coronary artery bypass grafts and wage- and severity-adjusted average cost.

We appreciate the considerable effort you and your staff members have put into the development and improvement of the inpatient prospective payment system (IPPS) and specifically recognize the need to continually evolve the payment system to reflect the current landscape within the field of medical services. We further recognize the significant complexities associated with gathering reasonably accurate cost data – data that should serve as the foundation of payment systems such as the proposed IPPS.

Origins of the Proposal

CMS is proposing to make the most significant changes to the hospital inpatient payment system since the late 1980s. The proposed changes appear to have their roots in the Medicare Payment Advisory Commission's (MedPAC) 2005 Report to Congress on Medicare payments for a certain subset of "specialty" hospitals. The MedPAC report raised concerns that the specialty hospitals were selecting the most profitable cases in their area and leaving the other acute care hospitals with less profitable services. Rather than addressing this issue of specialty hospitals in independent fashion, MedPAC recommended changing the payments for ALL acute care hospitals to reduce the incentives in the overall inpatient payment system that fueled the growth of specialty hospital facilities.

CMS should certainly weigh the issues and concerns raised in the MedPAC report when considering policy changes. However, the proposed changes to the inpatient payment system are the equivalent of throwing the baby out with the bath water. Efforts to address issues identified in the MedPAC report should begin and end with the specialty hospital subset and should not occur in conjunction with payment systems at large for all other hospital facilities.

Issues with the proposed IPPS

Setting aside the issues associated with specialty hospitals, Baptist Hospital notes two major areas of concern with the proposed IPPS. First, the proposal incorporates an estimated "cost-based" system, rather than a charge-based system for determining the payment weights for each patient category in 2007. Second, the proposal endeavors to change the method of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Proposing both changes in a single regulation, with implementation in 2007, is unprecedented.

Estimated, not Actual, Costs

CMS proposes to base payments on "costs". In many senses, this is a positive move and is consistent with how private insurers handle costs associated with technology. However, the primary difference between CMS's proposed methodology and the private insurers is the timing of cost data. Private insurers are utilizing data in real-time and are paying actual invoice costs for technology used in the care of patients. In CMS's

proposal, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat patients, rather it is a rough approximation of costs. To calculate the cost estimates for Fiscal Year 2007 payments, CMS proposes to utilize hospital claims data from Fiscal Year 2005 and hospital cost reports from Fiscal Year 2003. The cost reports provide the actual costs and the actual charges for all patients (non-Medicare and Medicare patients). The use of any data from Fiscal Year 2003 fails to account for current technology costs – namely drug-eluting stents and bi-ventricular pacemakers/defibrillators, mainstays in the cardiac care landscape. As such, the estimates on cost that CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for the care of Medicare patients.

It is widely known that hospitals across the country do not use a uniform approach to mark-up strategies for technology. Higher cost technologies, such as those used in the treatment of cardiac patients, are often marked up a lower rate than lower cost items. This leads to an inappropriate reflection of cost when attempting to apply derived averages. The following table demonstrates this principle and points out that high-cost technology such as defibrillators and drug-eluting stents would be unfairly accounted for in the proposed reimbursement methodology, causing hospitals to lose substantially with these technologies. This example also highlights why cost reports were never intended to be utilized for the sake of developing accurate procedure specific payment rates.

Impact of Assuming Uniform Mark-up in Estimating Costs

	Acquisition Cost	Actual Hospital Mark-Up	Charges After Mark-Up	CMS Derived Average Mark-Up	CMS Estimated Costs Based on Avg Mark-up	Delta Between CMS to Actual
Dual Chamber ICD	$20,000	200%	$40,000	267%	$14,998	$5,002
Bi-Ventricular ICD	$28,000	200%	$56,000	267%	$20,997	$7,003
Drug-Eluting Stent	$2,500	200%	$5,000	267%	$1,875	$625
Other supplies	$8	400%	$32	267%	$12	($4)

Gross Impact on Cardiac Care

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services. These proposed reductions to cardiac services are severe and are not rooted in any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to

pursue a better understanding of actual costs to treat cardiac patients, any such efforts must be made with the intention of producing accurate information – the end result may well be an alteration in the existing infrastructure for cardiac services reimbursement. However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be grave and may potentially limit patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). This is clearly not what CMS intends to achieve with this proposal. As such, delaying the implementation of any changes to cardiac services reimbursement until such time as accurate and appropriate information regarding costs to treat and manage patients with cardiovascular diseases can be compiled is the only prudent approach that can be taken.

Summary

Again, Baptist Hospital appreciates the opportunity to provide our commentary on the 2007 CMS IPPS proposal. Baptist Hospital remains fully supportive of prospective payment for hospital inpatient services, and commends CMS for its ongoing efforts to ensure adequate reimbursement for all clinical services. Moreover, we recognize the extremely complex issues involved in establishing appropriate reimbursement for procedures performed in the inpatient setting. As such, Baptist Hospital remains committed to working with CMS and other affected parties to ensure that hospitals remain able to provide access to high quality cardiovascular care involving cutting-edge technologies in all settings of care. Finally, Baptist Hospital supports CMS's efforts to ensure that Medicare beneficiaries have continued access to high quality, efficient, and effective cardiovascular services.

Sincerely,

L. Andrew Terry

L.Andrew Terry
Vice President
Baptist Health Care

W. L. GORE & ASSOCIATES, INC.
1505 NORTH FOURTH STREET • P.O. BOX 2400 • FLAGSTAFF, ARIZONA 86003-2400
PHONE: 928/526-3030 • FAX: 928/526-3815

June 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
7500 Security Blvd, Mail Stop C4-26-05
Baltimore, MD 21244-1850

Subject: File code CMS-1488-9: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

W.L. Gore & Associates, Inc. (Gore) is pleased to provide the attached comments on the proposed rule. Since 1974, Gore has developed, manufactured and sold implantable medical devices, with a focus on cardiovascular implants for traditional surgical vascular repair and recently, the less invasive endovascular approach for the repair of Aortic Aneurysms.

Endovascular Aortic Repair (EVAR) is relatively new and rapidly evolving; in fact upon implementation of IPPS 2007, Gore's "TAG" device for endovascular repair of Thoracic Aneurysm will enter its second year of "New Technology Status." In part, the relative "newness" of this technology may account for some of the significant issues raised by the proposed rule, and addressed in the attached comments:

1) **Classification** - EVAR procedures are inappropriately classified in the proposed consolidated APR-DRG patient classification system. We recommend preserving the current classification logic, grouping EVAR and Surgical treatment together (Attachment A).

2) **Severity of Illness** - Patients undergoing EVAR procedures are inappropriately and disproportionately assigned to very low Severity of Illness (SOI) levels. We recommend eliminating artificially low SOI levels that do not capture the inherent complexity of these cases. (Attachment B)

3) **Cost basis** - Hospital costs for EVAR technology is significantly underestimated using the proposed HSRV methodology. We recommend several methods that can be used to improve the accuracy of supply/equipment costs. (Attachment C)

If implemented as proposed, the combined impact on reimbursement for a hospital with a typical EVAR caseload will approach, or exceed, a 40% reduction from current levels. This is far beyond the incremental profit or loss situation that hospitals expect to experience, or can tolerate, in a prospective payment system. Patient access will be severely reduced, with a resulting shift back to traditional surgery – longer stays, more ICU, and greater nursing requirements.

Our goal with these comments is to illustrate, by way of example, the impact of very complex and compounding issues on a specific set of services. We look forward to the opportunity to provide additional detail and have further discussion in support of our comments.

Sincerely,

Don Goffena
Reimbursement Affairs
W.L. Gore & Associates, Inc.
928-864-2826

ATTACHMENT A

Reference: CMS-1488-P: "Refinement of DRGs: Severity of Illness"

COMMENT 1

Base classification of cases with procedures 39.71, 39.73 to proposed APR-DRG "Major Abdominal Procedures", is more appropriate than the currently proposed base classification.

The proposed rule contemplates utilization of a modified APR-DRG ("cAPR-DRG") patient classification system for the purpose of improving the correlation of reimbursement to a patient's clinical status and treatment. This comment recommends a correction regarding the proposed base classification for two relatively new surgical procedures within MDC 05:

1) **ICD-9 39.71** Endovascular implantation of graft in abdominal aorta (EVAR-AAA).
The base classification for this procedure would be more appropriately made to "Major Abdominal and Thoracic Procedures" (cAPR-DRG 225-227). Under the current proposal, 39.71 is inappropriately assigned to base classification "Other Vascular Procedures" (cAPR-DRG 234-236).

2) **ICD-9 39.73** Endovascular implantation of graft in thoracic aorta (EVAR-TAA).
Under the current proposal, procedure 39.73 is not recognized as a valid procedure code. The base classification for this procedure would be appropriately made to "Major Abdominal and Thoracic Procedures" (cAPR-DRG 225-227).

These major points support the recommended correction of base classification:

- Repair of the great vessels (aorta), whether by endovascular or the corollary traditional open surgical technique, currently share the same base DRG classification "Major Cardiovascular Procedures", DRG 110/111.
- The continued classification of aortic aneurysm repair distinct from peripheral vessel repair recognizes the significant clinical differences in disease state and treatment required.
- Resources used in the endovascular repair of the great vessels are significantly greater than those used in peripheral vessel repair.

Without correction, the proposed changes will reduce payment for the typical hospital EVAR case load by an estimated 42% (Table 1). Hospitals will drastically restrict and/or eliminate the service. The resulting shift back to open surgery as the only financially viable treatment alternative will increase the length and intensity of stay, countering efforts of the healthcare system to reduce the need for more hospital beds and scarce nursing resources.

Table 1: Net Impact of classification for Abdominal Aortic Aneurysm (AAA) Repair in cAPR-DRG*

	39.71 Endovascular Repair AAA		**38.44 Open Surgical Repair, AAA**	
2006 CMS-DRG (Classification: Major CV Procedure)	DRG (RW)	% of Discharges	DRG (RW)	% of Discharges
	110 (3.9587)	66%	110 (3.9587)	85%
	111 (2.4488)	33%	111 (2.4488)	15%
Weighted Avg RW (e$)***	3.4208 ($16,185)		3.7322 ($17,659)	
	39.71 Endovascular Repair AAA**		**38.44 Open Surgical Repair, AAA**	
CMS Proposed APR-DRG (Classification: Other Vascular Procedure)	234 (1.5918)	44%	225 (1.9777)	10%
	235 (2.0045)	44%	226 (2.6456)	50%
	236 (3.1716)	7%	227 (3.8085)	27%
	205 (6.7708)	2%	205 (6.7708)	13%
Weighted Avg RW (e$)***	1.9957 ($9747)		3.4269 ($16738)	
Net change in RW (e$)***	-42% (-$6960)		-8% (-$1,491)	

* ICD 9 39.71 and 38.44, both with primary diagnosis 441.4, 2004 Medpar data

** Expected distribution to severity levels per Supplemental 2004 Medpar file. *** Estimated dollars for 2006 based on OSA $4731; est. for proposed APR-DRG based on proposed 2007 operating standardized amount, full update, $4884.

SUPPORT FOR THE COMMENT

Background - ICD-9 procedure code 39.71 was implemented in October 2000, describing the endovascular graft repair of Abdominal Aortic Aneurysm (EVAR-AAA). Effective October 2005, ICD-9 code 39.73 was implemented, recognizing the approval of this "interventional" technique for repair of Thoracic Aortic Aneurysms (EVAR-TAA). This new class of surgical technology provides recognized societal, patient and physician goals – reduced hospital stay and intensity, reduced risk of complications and death resulting from treatment, and an alternative for many patients for whom limited or no suitable options were previously available. EVAR technology accomplishes this by utilizing catheter-based techniques with advanced radiologic and ultrasound imaging to minimize the invasive nature of traditional open surgery – smaller incisions, reduced cardiopulmonary bypass and anesthesia, and less blood loss. The significance of EVAR has manifested in other ways – the implementation of the "SAAAVE" AAA screening benefit to increase early detection, management and timely treatment of this deadly disease; and the implementation of "New Technology Status" for EVAR-TAA in order to help hospitals adopt this costly new technology as they transition from the high labor content required for traditional surgical care to more complex "technology content" represented by interventional techniques.

Current vs. Proposed Base Classification: Net Impact - Under both the current CMS and the proposed cAPR-DRG system, assignment of surgical cases is made based on the reason for admission and the type of procedure performed. We propose that the logic which currently groups both 39.71 and 39.73 ("EVAR"), and the corollary traditional open surgical approach (38.44, 38.45), to the same base DRG classification is the most appropriate, and should be applied in the cAPR-DRG system, if adopted.

This logic exists elsewhere in the proposed cAPR-DRG. For example, both surgical bypass of lower limb vessels for occlusion (39.29) and corollary interventional procedure (39.90 non-coronary PTA, with or without stent 39.90) are classified to cAPR-DRGs 234-236, "Other Vascular Procedures".

Table 1 demonstrates the dramatic impact resulting from classification of EVAR-AAA from current DRG 110/111 "Major Cardiovascular Procedures", to the proposed APR-DRG "Other Vascular Procedures". The reduction for EVAR-TAA is similar in magnitude. Such a dramatic change will encourage a shift back to nursing intensive, prolonged hospital stays.

Table 1: Net Impact of classification for Abdominal Aortic Aneurysm Repair in cAPR-DRG*

	Endovascular Repair 39.71, AAA		**Open Surgical Repair 38.44, AAA**	
2006 CMS-DRG (Classification: Major CV Procedure)	DRG (RW)	% of Discharges	DRG (RW)	% of Discharges
	110 (3.9587)	66%	110 (3.9587)	85%
	111 (2.4488)	33%	111 (2.4488)	15%
Weighted Avg RW (e$)***	3.4208 ($16,185)		3.7322 ($17,659)	
	Endovascular Repair 39.71, AAA**		**Open Surgical Repair 38.44, AAA**	
CMS Proposed APR-DRG (Classification: Other Vascular Procedure)	234 (1.5918)	44%	225 (1.9777)	10%
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Net change in RW (e$)***	-42% (-$6960)		-8% (-$1,491)	

* ICD 9 39.71 and 38.44, both with primary diagnosis 441.4, 2004 Medpar data

** expected distribution to severity levels per Supplemental 2004 Medpar file *** Estimated dollars for 2006 based on OSA $4731; est. for proposed APR-DRG based on proposed 2007 operating standardized amount, full update , $4884

Proposed cAPR-DRG assignment clinically inappropriate - Based on the majority of procedures and diagnoses which make up proposed cAPR-DRG "Other Vascular Procedures", assignment of EVAR to this classification is not appropriate. This classification consists almost exclusively of treatments for occlusive pathologies of the lower limb; these have a far different clinical intensity than treatment of aneurysm pathologies performed in the abdominal (AAA) or thoracic cavity (TAA).

Table 2 demonstrates that base classification "Other Vascular Procedures" essentially consists of non-coronary, non-great vessel procedures, with the exception of 39.71.

Table 2: Majority Procedures in base classification cAPC-DRG "Other Vascular Procedures"
(top ±80% shown)

Primary Procedure	Description	Discharges in cAPR-DRG 234	235	236
3950	ANGIO OTH NON-CORONARY	12,758	17429	10556
3929	VASC SHUNT & BYPASS NEC	11,087	15319	10067
3971	ENDO IMPL GRFT ABD AORTA	5,694	5882	1252
3949	VASC PROC REVISION NEC	2,119	5828	2942
3818	LOWER LIMB ENDARTERECT	1,794	2098	999
3803	UPPER LIMB VESSEL INCIS	1,304	59	411
3808	LOWER LIMB ARTERY INCIS	852	1987	1077

2004 supplemental Medpar file

Similarly, Table 2A shows that peripheral atherosclerosis; embolism or other peripheral occlusive pathologies represent the majority "reason for admission" (i.e. primary diagnosis) within this classification.

Table 2A: Majority Diagnoses in base classification cAPC-DRG "Other Vascular Procedures"
(top ±80% shown)

Primary Diagnosis	Description	Discharges in cAPR-DRG 234	235	236
44021	ATH EXT NTV AT W CLAUDCT	9,135	7645	899
4414	ABDOM AORTIC ANEURYSM	5,757	5860	971
99674	COMP-OTH VASC DEV/GRAFT	2,697	5978	1685
44422	LOWER EXTREMITY EMBOLISM	2,624	3770	1703
4439	PERIPH VASCULAR DIS NOS	2,361	2619	845
44022	ATH EXT NTV AT W RST PN	2,344	3770	692
4471	STRICTURE OF ARTERY	2,281	2380	483
44023	ATH EXT NTV ART ULCRTION	2,021	4681	1686
44020	ATHSCL EXTRM NTV ART NOS	1,892	2051	416
44421	UPPER EXTREMITY EMBOLISM	1,114	127	304
4423	LOWER EXTREMITY ANEURYSM	774	1054	208
44031	ATH EXT AUTOLOGS BPS GFT	731	842	240
9961	MALFUNC VASC DEVICE/GRAF	444	1123	352
4422	ILIAC ARTERY ANEURYSM	391	427	70
44030	ATHSCL EXTRM BPS GFT NOS	339	407	126
99662	REACT-OTH VASC DEV/GRAFT	152	2203	2425
44024	ATH EXT NTV ART GNGRENE	-	1184	6638
44481	ILIAC ARTERY EMBOLISM	-	582	154
9972	SURG COMP-PERI VASC SYST	-	555	198

Resource utilization - The significant difference in treating the non-coronary, peripheral cases in base classification "Other Vascular Procedures" versus EVAR is supported by the difference in resources consumed. Table 3 shows that EVAR-AAA cases have from one-third to more than double the average charge for all other procedures in 234-236. This contributes the relatively high COV. Likewise, EVAR-TAA shows an even greater difference in average charge; a finding that is not unexpected since EVAR-TAA met the significant "increased cost" threshold for the New Technology DRG Add-On payment.

Table 3: Avg. Charge* for EVAR vs. all other Cases Classified to 234-236		
234 OTHER VASCULAR PROCEDURES SOI 1 (COV charges: .7261)		
	EVAR-AAA: 39.71 w/441.4	$54,800
	EVAR-TAA: 39.79 w/441.01.441.1,441.2 **	$60,700
	All other surgical procedures in cAPR-DRG 234	$26,600
235 OTHER VASCULAR PROCEDURES SOI 2 (COV charges: .7729)		
	EVAR-AAA: 39.71 w/441.4	$61,100
	EVAR-TAA: 39.79 w/441.01.441.1,441.2**	$61,100
	All other surgical procedures in APR-DRG 235	$35,178
236 OTHER VASCULAR PROCEDURES SOI 3 (COV charges: .8753)		
	EVAR-AAA: 39.71 w/441.4	$82,200
	EVAR-TAA: 39.79 w/441.01.441.1,441.2**	$100,900
	All other surgical procedures in APR-DRG 235	$59,400
*claim charges from 2004 Supplemental Medpar all claims; not standardized		
** 39.79 w/TAA Diagnoses used to identify EVAR-TAA. Charges for Endo TAA will be conservative (low) due to clinical trial (pre-commercial) status in 2004.		

ATTACHMENT B

Reference: CMS-1488-P: "Refinement of DRGs: Severity of Illness"

COMMENT 2

Severity of Illness (SOI) for cases involving procedures 39.71, 39.73 should at minimum be level 2 or higher, reflecting inherent "complexity" of the patient condition and treatment used.

The proposed rule acknowledges that the proprietary algorithm used to determine severity of illness levels may not recognize the "complexity" of treatment, resulting in an SOI that does not appropriately accounting for the resources used. This comment suggests a simple adjustment to the algorithm:

> **ICD-9 39.71** Endovascular implantation of graft in abdominal aorta (EVAR-AAA), and
> **ICD-9 39.73** Endovascular implantation of graft in thoracic aorta (EVAR-TAA), within the appropriate base DRG classification (addressed in separate comment), should assign to SOI level 2 and higher, at minimum.

The following points support this suggestion:

- While the SOI algorithm confirms that EVAR treatment reduces treatment-related complications and concurrent patient severity, it does not acknowledge the hospitals resources used to achieve that improvement.
- The "complexity" of EVAR cases, as measured by the surgical supplies used, are:
  - essentially independent of SOI,
  - represent 1/3-1/2 of total case charge,
  - represent a Relative Weight of ± 3 before any other costs (hospital days, etc.) are considered (using CF of ± $4800).

The elimination of SOI levels inadequate to cover at minimum hospitals supply costs for EVAR 39.71 and 39.73 will reduce this inequity.

SUPPORT FOR THE COMMENT

The clinical literature generally characterizes patients being considered for EVAR or Open Surgical (OS) repair as having similar comorbid conditions. A review of almost 3000 clinical trial patients followed in the Lifeline Registry[1] summarizes EVAR patients as slightly older and having more cardiac comorbidities than the counterpart surgical group. With the exception of a small sub-population of patients who may have conditions putting them at high risk for OS, the preponderance of clinical experience indicates that patients being considered for treatment (e.g. before admission) with EVAR or OS are clinically similar.

In contrast, the proprietary SOI algorithm characterizes EVAR patients upon discharge as significantly less severe than OS patients (Table 1). Severity as assessed by the SOI, confirms the clinical experience, demonstrating that EVAR treatment accomplishes its purpose – a reduction in the risk of procedure-related complications (i.e. infection) which lead to higher SOI levels.

Table 1: SOI for EVAR and Surgical Repair for Aneurysm (AAA only shown)

APR-DRG (RW)	EVAR-AAA (39.71 w/441.4)	Severity level	Surgical AAA (38.44 w/441.4)	APR-DRG (RW)
234 (1.5918)	44%	SOI 1	10%	225 (1.9777)
235 (2.0045)	44%	SOI 2	50%	226 (2.6456)
236 (3.1716)	7%	SOI 3	27%	227 (3.8085)
205 (6.7708)	2%	SOI 4	13%	205 (6.7708)

The shortcoming of the SOI is that it does not recognize "value" in the complications that are avoided, nor the resources consumed in avoiding them. As proposed, severity classification will penalize hospitals for offering EVAR treatment minimizing complicating conditions.

Table 2 shows that resources (measured as charges) for the "supply" (e.g. mostly implant device in EVAR) are constant and independent of SOI. Different from non-EVAR cases, these charges represent a significant portion of total resources. The difference in resource, whether expressed as cost or charge, is a valid measure of "complexity" and should be a factor in establishing appropriate SOI levels for EVAR.

Table 2: Charges for EVAR and Surgical Repair of Aneurysm (AAA only shown)

APR 234, SOI level 1	**Total chg**	**Supply chg**	**Supply %**
EVAR-AAA (39.71 w/441.4)	$54,800	$32,000	58%
All other cases	$26,600	$6,500	24%
APR 235, SOI level 2			
EVAR-AAA (39.71 w/441.4)	$61,100	$33,400	55%
All other cases	$35,200	$7,000	20%
APR 236, SOI level 3			
EVAR-AAA (39.71 w/441.4)	$82,200	$31,800	39%
All other cases	$59,400	$8,200	14%

The impact of artificially low SOI assignment is drastic. Using EVAR-AAA as an example, Table 3 shows that under the proposed SOI and classification, reimbursement at level 1 and 2 is inadequate to cover even the estimated average implant device cost. Because device utilization is relatively constant, and not linked to SOI, the lowest SOI for EVAR should be established at a level that better reflects the base costs. SOI level 1 in any DRG classification is inadequate.

Table 3: Est. Reimbursement vs. Known Supply (Implant Device)

APR 234, SOI level 1 only	**Total chg**	**Est. Reimb.***	**Implant Cost**
EVAR-AAA (39.71 w/441.4)	$54,800	$7,800	$13,682
APR 235, SOI level 2			
EVAR-AAA (39.71 w/441.4)	$61,100	$9,800	$13,682
APR 236, SOI level 3			
EVAR-AAA (39.71 w/441.4)	$82,200	$15,500	$13,682

* using operating standardized amount, as proposed for 2007 (± $4880)

Note on "implant cost" derivation: data source Hospital Supply Index, IMS Health, Inc., Dec. 2005. By manufacturer, "Base" implant components as required to build aorto/bi-iliac prosthesis; supplemental devices (extensions, etc.) allocated uniformly across number of base devices. Invoice cost of base + supplemental then weight-averaged by manufacturer market share of 4 manufacturers.

Recommendation - For procedures 39.71 and 39.73, case "complexity" should be recognized by charges or cost, and SOI levels representing Relative Weights significantly below that threshold should not be assigned.

ATTACHMENT C

Reference: CMS-1488-P, comments on "HSRV weights"

COMMENT 3

For procedures 39.71 and 39.73, application of a "supplies and equipment" Cost/Charge Ratio (CCR) of .34 results in estimates of TOTAL supply cost less than actual implant device cost alone.

The proposed rule contemplates using a single CCR of .34 to derive hospital supply/equipment "cost" from claim charges, as part of a shift from charge to "cost" as the basis for setting DRG relative weights (and hence payment). For cases involving procedures 39.71 and 39.73, where the implant device alone represents more than half of total supply charges, the result of applying a CCR of .34 is a dramatic underestimation of the hospital's true cost. The subsequent calculation of Relative Weights for the associated DRGs (or APR-DRGs) results in a built –in penalty for hospitals providing these cases.

Table 1 illustrates this discrepancy. Using a CCR of .34, the total imputed cost of the hospital's consumption of ALL equipment and supplies is EXCEEDED by the known (and verifiable) invoice cost of the Implant Device only:

- For 39.71 (EVAR-AAA) the average implant-only invoice cost exceeds the estimated total supply cost by 20-30%
- For 39.73 (EVAR-TAA, proxy 39.79/441.2 in 2004) the average implant-only cost exceeds the estimated total supply cost by over 200%. This despite the fact that during the clinical trial status in 2004, many hospitals did not charge for the category B investigational device.

Table 1: Comparison of Actual Average Invoice Cost for Implant Device Only vs. Imputed All Device/Supply Cost

2008 Proposed cAPR-DRG	Medpar Case Total Charges	Medpar ALL Supply/Equip Charges	TOTAL Est. Supply "Cost" Via CCR .34*	DEVICE Only Actual Avg. Invoice Cost**	DEVICE Cost >> Total Est. Cost
234 OTHER VASCULAR PROCEDURES SOI 1					
39.71 EVAR-AAA** w/441.4	$54,778	$32,045	$10,895	$13,682	+26%
39.73 EVAR-TAA *** (2004 proxy 39.79/441.2+)	$60,687	$27,307	$9,284	$20,400	+219%
All other procedures APR-DRG 234	$26,587	$6,523	$2,218	--	
235 OTHER VASCULAR PROCEDURES SOI 2					
39.71 EVAR-AAA** w/441.4	$61,066	$33,433	$11,367	$13,682	+20%
39.73 EVAR-TAA*** (2004 proxy 39.79/441.2+)	$61,107	$21,554	$7,328	$20,400	+278%
All other surgical procedures APR-DRG 235	$35,178	$7,015	$2,385	--	
236 OTHER VASCULAR PROCEDURES SOI 3					
39.71 EVAR-AAA ** w/441.4	$82,176	$31,842	$10,826	$13,682	+26%
39.73 EVAR-TAA *** (2004 proxy 39.79/441.2+)	$100,898	$27,055	$9,199	$20,400	+222%
All other surgical procedures APR-DRG 235	$59,413	$8,160	$2,774	--	

*From 2004 Supplemental Medpar, for "Supplies and Equipment" charge line items

**** For AAA cases**, invoice data source: Hospital Supply Index, IMS Health, Inc., Dec. 2005. Average cost of device/case as follows:
1. "Base" endoprosthesis for each of 4 manufacturers based on components required to implant full AAA device (1 Aortic trunk, 2 Iliac limbs)
2. "Ancillary" endoprosthesis (i.e. extensions, cuffs, etc.) utilization and prices (per manufacturer) are averaged across number of base units sold
3. Average IMPLANT DEVICE cost is weight-averaged by market share of 4 companies:
company A: 39%; company B: 32%; company C: 28%, company D: 1%

***** For TAA cases**, costs from 2005 submission for New Technology DRG add-on, W.L. Gore & Associates, Inc. Proxy code in 2004 was 39.79 with diagnoses TAA

Recommendation - The following techniques would improve the precision of a cost-based methodology:

1) Use publicly available hospital invoice cost data to confirm average estimated implant device cost.
2) Use claims from the 5% inpatient standard analytic file to provide a more detailed understanding of supply charges at the line-item level.
3) Use statistical techniques to establish differential "sub-CCRs" that address low-cost and high-cost devices in a manner more consistent with actual hospital practice (i.e. $10,000 devices are not marked up the same as a $100 guidewire).
4) Establish an "implant prosthesis only" revenue center (i.e. 278), so that a CCR could be developed with specificity for the generally more costly implantable devices.

130

TMC
TRUMAN MEDICAL CENTERS

Department of
Corporate Finance
2301 Holmes
Kansas City, MO 64108

816-404-3528

June 9, 2006

Dr. Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1488—P — Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates; Proposed Rule.

RE: DRG Reclassifications; EMTALA; Resident Time Spent in Non-patient Care Activities as Part of Approved Residency Programs; Outlier Payments; Health Information Technology; Hospital Quality Data; Value-Based Purchasing

Dear Dr. McClellan:

Truman Medical Centers (TMC) appreciates the opportunity to submit comments on the above-captioned Proposed Rule. [1] Truman Medical Centers are academic health centers in Kansas City, Missouri providing state of the art, quality health care to our community regardless of ability to pay. As the Kansas City community's core safety net hospital system, the majority of our patients are uninsured or underinsured. Our comments follow:

HOSPITAL HILL

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BEHAVIORAL
HEALTH
NETWORK

- TMC supports CMS' policy goal to increase the accuracy of current IPPS payment methodologies, and we urge CMS to implement all DRG changes effective October 1, 2006. Such accuracy is critical to the financial stability of safety net providers who provide care without regard to the relative profitability of IPPS payments. In order to ensure the most accurate system possible, we encourage CMS to validate Hospital Specific Relative Value (HSRV) weighting using hospital cost data.

- It is critical that CMS not delay implementation of changes to the DRG system beyond October 1, 2006. For example, mental health services have been underpaid by the Medicare program for many years causing a mental

health crisis in the Kansas City community where more than two-thirds of psychiatric beds have closed in recent years. The shortage of inpatient mental health has resulted in the overcrowding of TMC's emergency room, as well as affecting our inpatient capacity.

- TMC also supports movement to the new CSA-DRG system scheduled for implementation in October 2007.

- TMC urges CMS to instruct Medicare fiscal intermediaries to capture all diagnosis and procedures codes available under the HIPAA electronic transaction standards.

- TMC strongly supports CMS' proposal to apply Emergency Medical Treatment and Labor Act (EMTALA)[2] transfer requirements to hospitals without dedicated emergency departments. We strongly concur with CMS that EMTALA requires that all hospitals with the capability to accept EMTALA transfers do so regardless of whether the facility has a dedicated emergency department. We also urge CMS to more closely study emergency transfer patterns of affiliated hospitals, and, if appropriate, prohibit through regulation the selective transfer of patients based on insurance status. In addition, we also request that CMS establish through regulation a minimum threshold of on-call coverage to ensure that hospitals fulfill their EMTALA obligations to provide emergency screening and stabilization services to all patients.

- TMC urges CMS to rescind its clarification in the Proposed Rule related to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

- TMC opposes raising the outlier threshold and supports the American Hospital Association's (AHA's) recommendation to utilize a methodology that incorporates both *cost* inflation and *charge* inflation in calculating the outlier threshold. We believe the use of more than one indicator will make the threshold calculation more accurate and reliable. To account for the unspent outlier payments and attendant understated standardized amounts, TMC urges CMS to retroactively adjust IPPS payments.

- TMC believes that CMS has broad statutory authority to encourage and facilitate widespread adoption of health information technology (HIT) through broad federal support such as a comprehensive "Hill-Burton HIT Initiative." Safety-net providers such as TMC that receive a significant portion of their revenue through federal health care dollars and that operate with limited resources should be one of the primary recipients of federal HIT funding, particularly because low income and indigent patients treated by the safety net are more likely to directly benefit from HIT reforms than other patient groups. TMC supports HIT demonstration projects targeted at building an interoperable, national network of safety net providers.

- TMC joins the AHA and the National Association of Public Hospitals in urging that CMS require that hospitals only *prospectively* submit newly expanded quality measures. Thus, we request that CMS require hospitals seeking a full market basket update to start submitting the relevant data for all 21 measures for patients discharged beginning on or after July 1. We also strongly urge CMS to review on a case by case basis any incidence where a hospital's payment would be put in jeopardy as a result of the validation process.

- Finally, with regard to the development of pay-for-performance measures and value-based purchasing systems, CMS should ensure such metrics include quantification of the disparities in care experienced by patients of different races, ethnicities, and socioeconomic backgrounds.

TMC appreciates the opportunity to submit these comments on the Proposed Rule. If you have any questions about these comments, please contact me at (816) 404-3528.

Sincerely,

Allen M. Johnson
Chief Financial Officer

AMJ/gg/sh

[1] The Consolidated Omnibus Budget Reconciliation Act of 1985, P.L. 99-272.
[2] 71 Federal Register 23996 (May 25, 2006). Hereinafter "Proposed Rule."

Thomas Jefferson University Hospital

Jefferson Health System®

Thomas J. Lewis
President and
Chief Executive Officer

VIA OVERNIGHT MAIL

June 9, 2006

Thomas Jefferson University Hospitals

Thomas Jefferson University Hospital

Methodist Hospital

Jefferson Hospital for Neuroscience

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: **CMS-1488-P "Resident Time in Patient Activities" and "DRG Weighting and Classification Systems"**

Dear Administrator McClellan:

Thomas Jefferson University Hospital (TJUH) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. We also strongly urge the Agency to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY 2008.

Resident Time in Patient Activities

The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care". The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. Furthermore, the ACGME Common Requirements define Duty Hours as "...all clinical and academic activities related to the residency program, i.e., patient care (both inpatient and outpatient), administrative duties related to patient care, the provision for transfer of

patient care, time spent in-house during call activities, and scheduled academic activities such as conferences. Duty hours do not include reading and preparation time spent away from the duty site." We support the Agency's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs.

Proposed Changes to the DRG System

Restructuring the DRG system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals. Implementation of a "cost-based" DRG weighting methodology should be postponed for one year to allow for further work. This change should then be implemented simultaneously with an appropriate expansion of the current DRGs. In addition, a significant transition period must accompany these changes given the magnitude of this proposed policy change.

We urge the Agency to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs. We also urge the Agency to delay implementing both the proposed DRG reclassification and the change to the cost-based DRG weighting methodology until FY 2008 and allow for a significant transition period associated with this policy change.

We thank you for the opportunity to share our comments on Resident Time in Patient Activities and the DRG provisions of the proposed IPPS rule.

Sincerely,

Thomas J. Lewis
President and Chief Executive Officer

TJL:HJL:g

132

DEBORAH.
Hospital Foundation

DEBORAH.
Heart and Lung Center

John R. Ernst
President and CEO

Sent Via Federal Express

June 8, 2006

Dr. Mark McClellan
CMS Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1488-P

Dear Dr. McClellan:

The Administration of Deborah Heart and Lung Center would like this opportunity to comment on the " HSRV weights" and "DRG Reclassification sections of the Proposed Rule, 71 Federal Register 23996 (April 25, 2006). We have serious concerns regarding the implementation of the proposed rule as it refers to the recalibration of the DRG rates, especially as it affects an institution such as ours, which for over 80 years has continued its founding mission of caring for those in need, regardless of ability to pay. The impact of this change is very significant to our institution. We recalculated our payments with the proposed weights for our Medicare cases for the first 3 months of 2006. The impact was a loss of one and a half million dollars, annualized this means a six million dollar reduction in revenue! Deborah Heart and Lung Center has a very large indigent patient population that will unquestionably be put at risk should the proposed regulations be implemented.

We strongly urge you to delay implementing the proposed HSRV and DRG Reclassification sections of the proposed rule until the following issues are addressed:

Assignment of Lines Grouped from the Cost Report
This is a very important unresolved issue. Many hospitals break out the various sub-departments that make up cardiology and report them on different lines on the Cost Report. On our 2003 Cost Report we report cath lab costs on line 58.01. When the costs were grouped our cath lab costs were left out of lines 53/54 and our cardiology cost and charges were profoundly understated. We are sure many other hospitals have this same

problem. Beginning with our 2005 report we will fix this problem but it will be two years before CMS will use 2005 Cost Report data. However, because there are no uniform reporting requirements regarding this issue, undoubtedly some hospitals, even on their 2005 Cost Report, will still report cardiac costs on lines other than line 53 or 54.

Did CMS study the financial impact of combining multiple cost report cost centers into the ten "charge groups" denoted in the proposed rule? Were there any other combinations reviewed, and if so, were the outcomes similar? CMS should elaborate on the process it went through to derive the ten charge groups.

Revenue Codes to Assign Costs to Detail UB's

Yet another issue is the use of revenue codes to assign costs to detail UB's which is critical to the process of determining the average cost and reimbursement of each DRG. Before the advent of CPT-4 codes hospitals used UB revenue codes to identify where the various charges on the cost master were performed. When CPT-4 codes were introduced various edits were implemented to make sure that the revenue code and the CPT-4 code matched one another. As years went by technology changed, allowing many tests that were traditionally preformed only in one department to be done in various departments throughout the hospital. One minor example of this is blood gases. These tests are performed on the medical floors and in the operating room but they are given a lab revenue code. Why this becomes problematic is when a cost to charge ratio is developed and costs are assign to a UB, the costs and charges on the Cost Report may not match up to the UB because of the above mentioned problem. This and many other cost reporting issues may be avoided by staying with the charged based methodology. We suggest that the implantation be delayed until this and other cost report issues are resolved.

Medical Supply Costs and Charges

A third issue is with a hospitals' ability to correctly match its medical supply costs and charges. Hospitals are required to report all chargeable supplies to one cost center on the Cost Report. The problem is that most hospitals expense their supplies to each individual cost center. With the exception of items that have a large cost, it is very difficult to separate the chargeable supplies from the non chargeable supplies. We suspect that nationally the cost to charge ratio for supplies charged to patients is inaccurate. This may account why it would appear that Pacemakers and Defibrillators may not be cost accounted for accurately.

In many hospitals the charges for very high cost supplies such as defibrillators which cost $35,000 - $40,000 are set significantly lower than the cost to charge average of other supplies and services. Yet the proposed methodology assumes perfect uniformity. This erroneous assumption has caused the proposed DRG rate for defibrillators to barely cover the cost of the device and nothing more.

While in theory replacing a charge based system with a cost based system is desirable, when the new cost based system is in reality still based on charges accompanied with totally unproven assumptions, the result is one step forward and three steps backwards.

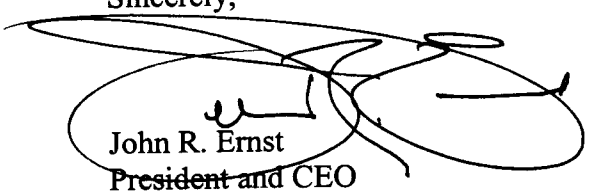
We believe that it is unlikely that changing from a charged based system to a true and tested cost based system could cause such a drastic shift in the DRG weighting factors that has resulted from the proposed changes. We looked at the MDC (Major Diagnostic Category) factors by major diagnostic category and we found that the only MDC that had a decline was MDC 5 cardiovascular services, and that MDC 5 is declining by a draconian amount. Billions of dollars are being shifted around based on unproven assumptions.

There were 12 MDCs that had an increase in weighting factors of more than 10% and 6 that had an increase of more than 25%. In order for the charges to be off this much the markup on cardiology services must be multiple times higher than other cost centers. We believe this to be unlikely. Has CMS looked at the overall cost to charge ratio for Cardiology compared to the cost to charge ratio for other services?

If the assumption is made that Cardiology services are marked up higher than other services one would question how much of patients' cost come from the cardiology department. In the example published in the federal register it indicated that 29 percent of a patients stay came from routine days (page 24011). Considering that open heart patients have a longer length of stay and significantly higher nursing costs than the average patient, we would assume that their percentage of room and board costs might be higher than 29%. Could a markup in just one cost center cause a misallocation of cost? It seems unlikely.

CMS has wisely postponed implementing the severity based DRGs until it can "debug" such a momentous undertaking. The severity DRGs are now scheduled for a 10/01/07 implementation date. Since the DRG re-weighting is much more complicated and requires uniform reporting and tested assumptions, none of which exist at this time, we strongly recommend and request a delay until at least 10/01/08 (FY09) and then strongly suggest a graduated 4-5 year phase in period. In addition we believe it makes more sense for CMS to implement HSRV after it implements the severity –adjusted DRG methodology because a DRG classification system takes place before a weight is assigned.

Sincerely,



John R. Ernst
President and CEO
Deborah Heart and Lung Center
Deborah Hospital Foundation

Susquehanna Health System
Divine Providence Hospital - Muncy Valley Hospital
The Williamsport Hospital & Medical Center

Richard W. DeWald
Chairman of the Board

Sister Joanne Bednar
Vice Chairman

Steven P. Johnson
President & CEO

133

June 9, 2006

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Published in the Federal Register on April 25, 2006

To Whom It May Concern:

Geographic Reclassifications

The following comments are being submitted on behalf of The Williamsport Hospital & Medical Center ("TWH") relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule (the "Proposed Rule") titled "Geographic Reclassifications." TWH strongly supports the advocated changes to the Medicare rules allowing for the reclassification of hospitals located in single hospital MSAs surrounded by rural counties. The Centers for Medicare & Medicaid Services ("CMS") should immediately adopt these changes to the urban county group reclassification regulations whereby a hospital in a single hospital MSA surrounded by rural counties, as described in more detail below, would be able to reclassify to the closest urban area that is part of a Combined Statistical Area ("CSA") located in the same State as the hospital.

In what we believe is only two areas of the United States today, there are individual urban hospitals[1] that are the sole hospital in their particular urban area (hospitals in single-hospital MSAs) that have historically found themselves surrounded by rural hospitals with whom they compete that receive higher Medicare payments because they have been reclassified to higher Medicare wage index areas or because CMS considers them rural referral centers, sole community hospitals, critical access hospitals or Medicare dependent hospitals (we will hereinafter refer to these hospitals as "hospitals located in a Single-Hospital MSA surrounded by

[1] Unless specified otherwise, the use of the term "hospital" or "hospitals" in this comment letter only refers to hospitals reimbursed under the prospective payment system.

rural counties").[2] Because these hospitals located in a Single-Hospital MSA surrounded by rural counties operate in urban areas that are not adjacent to any other urban area, they are unable to secure Medicare wage reclassification although they are at a competitive disadvantage because they are competing for labor with hospitals in nearby areas with higher wage indices. They cannot secure Medicare wage reclassification on an individual hospital basis under 42 CFR 412.230 because, according to CMS standards, they are too far from the nearest urban area[3] and, by definition, the ratio of a hospital in a single-hospital MSA's average hourly wage to the average hourly wage of hospitals in the area in which the hospital is located is always 100% and therefore, these hospitals can not meet the 108% threshold for urban hospitals. Similarly, these unique hospitals cannot secure Medicare wage reclassification on a county-wide basis under 42 CFR 412.234 because they are not adjacent to any urban area, for fiscal year 2007, are not part of a consolidated metropolitan statistical area ("CMSA") or combined statistical area ("CSA") that includes the urban area to which they seek redesignation, and for fiscal years 2008 and thereafter, are not part of a CSA that includes the urban area to which they seek redesignation.

Despite the fact that CMS has specifically stated that geographic reclassification is for hospitals that are disadvantaged by their current classification because they compete with hospitals that are located in the geographic area to which they seek reclassification,[4] and that the intent for its FY 2006 proposed changes to the urban group hospital reclassification criteria was "to preserve the reclassification opportunities for urban county groups,"[5] we believe CMS has failed to adequately address the inequities facing a specific subset of urban county groups, namely hospitals located in a Single-Hospital MSA surrounded by rural counties, in relation to the wage index and the rules governing geographic reclassification and is therefore failing to preserve the reclassification opportunities for all urban county groups. The advocated changes described in the Proposed Rule will enable CMS to adequately preserve the reclassification opportunities for urban county groups.

The Proposed Rule invited comments on three specific questions concerning the reclassification for hospitals located in a Single-Hospital MSA surrounded by rural counties.

1. What is the justification for reclassifying a hospital that is receiving a wage index reflecting its own wages?

A hospital, such as TWH, that receives a wage index reflecting its own wages is justified in seeking reclassification when its competitors have all been reclassified to and/or are located in an area that receives a wage index reimbursement that is significantly higher than the competitors' actual wages. The geographic reclassification rules have created an anomaly whereby a reclassified hospital may receive wage index reimbursement above its own average hourly wage. This excess reimbursement allows these reclassified hospitals to choose between

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[2] From our research, it appears that only TWH, located in Williamsport, Pennsylvania, Lycoming County (Williamsport, PA MSA) and Community Hospital, located in Grand Junction, Colorado, Mesa County (Grand Junction, CO MSA) meet the definition of hospitals located in a Single-Hospital MSA surrounded by rural counties.

[3] Urban hospitals must be within 15 miles of the urban area into which they seek reclassification for Medicare wage purposes. (Rural hospitals are permitted to be within 35 miles of the area to which they seek reclassification).

[4] June 4, 1991 Final Rule - 56 FR 25469; See also June 2, 1995 Proposed Rule – 60 FR 29202.

[5] May 4, 2005 Federal Register.

raising employees salaries or investing in new technology and services. The disadvantage for the hospital receiving a wage index reflecting its own wages that competes with the reclassified hospitals is that it must continually work to keep wages competitive while struggling to purchase new technology and continue to provide the services the Medicare beneficiaries in its community need.

Set forth below are specific examples of why TWH is justified in being reclassified despite receiving its own wage index, including an analysis of TWH's competitors and specific examples of how patient care and access to care will be adversely affected if TWH is not reclassified into the same MSA where its competitors are located and/or have been reclassified.

- TWH's competitor hospitals (in terms of proximity, comparability of services and other factors relevant to geographic reclassification) are Geisinger Medical Center ("Geisinger") and Evangelical Community Hospital ("Evangelical"), both of which have been reclassified into the Harrisburg MSA and thereby receive a higher wage index than TWH, placing TWH at a competitive disadvantage.

  - As shown on the map attached at Exhibit 1, Geisinger and Evangelical are the only PPS hospitals with which TWH competes that are located within 35 miles of TWH. Both Geisinger and Evangelical frequently use billboard, newspaper and radio advertising in Williamsport to recruit patients and staff to their facilities.

  - As shown on the Service Contrast Chart attached at Exhibit 2, the level of services TWH provides is close to that provided by Geisinger and substantially more than that provided by Evangelical. As also shown on the Service Contrast Chart, the level of services TWH provides is similar to that provided by Holy Spirit Hospital which is located in the Harrisburg MSA; and greater than that provided by Lock Haven Hospital, a rural hospital, and Mt. Nittany Hospital which is located in the State College MSA.

  - As shown on the Emergency Room Capability and Volume Chart attached at Exhibit 3, TWH has a significantly larger volume of emergency room visits than all the other hospitals in the region. TWH's volume of emergency room visits is comparable to the volume of emergency room visits of the hospitals located in the Harrisburg MSA, whereas the volume of Geisinger's and Evangelical's emergency room visits is substantially less than the volume of emergency room visits of the hospitals located in the Harrisburg MSA even though Geisinger and Evangelical have been reclassified into the Harrisburg MSA.

  - As shown on the Comparison of North Central PA Hospitals Chart attached at Exhibit 4, TWH's case/mix index is comparable to the case/mix index of the hospitals that are physically located in the Harrisburg MSA and/or have been reclassified into the Harrisburg MSA (e.g., Geisinger) and is notably more acute than the remaining hospitals in the region.

- Historically, TWH's base salary for entry level nurses was comparable to Geisinger's. However, Geisinger is currently able to offer a higher base salary for entry level nurses, a higher signing bonus for nurses[6] and a recent 12% increase in nurse salaries due to the fact that it receives a higher wage index than TWH. TWH's ability to recruit and retain nurses is negatively affected by its inability to offer similar benefits as a result of its receiving a lower wage index. In the long run, this makes it difficult, if not impossible, for hospitals located in a Single-Hospital MSA surrounded by rural counties to recruit and retain the qualified health care professionals they need to serve their communities. This concern is especially significant given the fact that TWH is the only hospital in its urban area and therefore has an even greater obligation to the communities they serve. Without necessary assistance from CMS, the long term financial viability of TWH is questionable.

- For the first time in five years, TWH experienced a significant reduction in its employees' job satisfaction as a result of TWH's inability to provide competitive wages and benefits, as evidenced by a recent internal employee opinion survey.

- TWH has only been able to remain viable and continue to compete with Geisinger and Evangelical in the level of services it provides as a result of the efficiencies TWH achieved through its affiliation (the "Affiliation") with Susquehanna Health System ("SHS") in 1994.7 These efficiencies were implemented over a 10-year period ending in 2004. Major cost reduction efforts included a 30% reduction in TWH's bed complement from 325 licensed beds to 225, and consolidation/reduction of administrative overhead and support services. In addition, of the 282 licensed beds at SHS's other two hospitals (Divine Providence Hospital and Muncy Valley Hospital) 80% or 226 beds were delicensed. As a result, the overall SHS licensed acute bed complement decreased from 607 to 325 or a 54% reduction. Now, with no additional costs left to cut and TWH's competitors continuing to receive higher wage indices, TWH is at a competitive disadvantage which will adversely impact the services that TWH is able to provide the community. While one might suggest that in a market place environment those hospitals with higher labor reimbursements may, in the future, offer additional or expanded services especially when TWH is forced to curtail them, convenient access to these services by less ambulatory seniors will be lost.

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[6] Geisinger is able to offer a signing bonus equal to $4,000 - $5,500 depending on the individual's willingness to work nights and weekends. TWH is only able to offer a $2,000 signing bonus.

[7] Prior to 1994, TWH and its health care affiliates operated as an independent health care system in the Williamsport area known as North Central Pennsylvania Health System ("NCPHS"). At the same time, inpatient and outpatient hospital and other medical services were also provided in the same area by Divine Providence Hospital of the Sisters of Christian Charity ("Divine Providence Hospital"), Muncy Valley Hospital and their affiliates as an independent health care system in the Williamsport area known as Providence Health Foundation ("PHF"). In 1994, the PHF and NCPHS systems, including Divine Providence, Muncy Hospital and TWH, combined their operations having concluded that the effective delivery of high quality, cost effective health care in North Central Pennsylvania required the integration of their operations. The combination was effectuated through the organization of Susquehanna Regional Health Care Alliance (which operates as SHS) and the delegation to SHS of responsibility for overall management and operation of the hospitals and their health care affiliates.

- If TWH is not reclassified into the Harrisburg MSA, TWH will not be able to retain its employees and patient care and access to care will be adversely affected as TWH is no longer able to make up the shortfall through any additional cost reduction efforts because it has already achieved a high level of efficiency as a result of the Affiliation. Based on calculations by an auditor engaged by the Pennsylvania Attorney General, SHS realized a net cost savings of $105 million dollars as a result of the Affiliation, yet SHS gave back 117% of its savings to the community in the form of low-cost or no-cost health care programs for the community, reduction in prices and/or limiting actual price increases for existing services, although it was only required by the Pennsylvania Attorney General to return 80% of the net cost savings it achieved as a result of the Affiliation to the community.

- Based on the fact that TWH's top competitors are Geisinger and Evangelical, both of which have been reclassified into the Harrisburg MSA, TWH has clearly demonstrated an economic connection to the Harrisburg MSA.

- TWH is a member of the Susquehanna Valley Rural Health Partnership ("SVRHP") a three-county rural health network of which TWH is the network referral facility. In this capacity, TWH supports a number of hospitals and a federally qualified health care center ("FQHC") including Muncy Valley Hospital, Bucktail Medical Center, Jersey Shore Hospital and Laurel Health which owns and operates the FQHC. If TWH is not reclassified into the Harrisburg MSA, TWH may no longer be able to support these health care organizations by providing IT services, hospital pharmacy services, medical transport services and physician continuing medical education programs.

2. Why should a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals that have received one form or another of special payment status relating to their rural locations, receive special treatment under the wage index?

A hospital should receive special treatment under the wage index when it is a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals ***with whom it competes*** (in terms of services provided, emergency room visits and case/mix) that have received one form or another of special payment status relating to their rural locations. Under these circumstances, the wage index reclassification rules interfere with a competitive market to the detriment of Medicare beneficiaries. A single hospital in an urban county must offer a broad range of services to meet the needs of the Medicare beneficiaries in its large service area while competing with hospitals that offer fewer services yet receive increased reimbursement due to their ability to reclassify. This is exactly the type of situation the geographic reclassification process is designed to address but, due to its unique location, a single hospital in an urban county is unable to reclassify through the general reclassification process.

CMS has consistently recognized the need to provide special treatment for certain hospitals in relation to the wage index and the rules governing geographic reclassification. Most recently, under Section 508(a) of the Medicare Prescription Drug, Improvement and

Modernization Act enacted on December 8, 2003, CMS attempted to "alleviate large disparities in wage indices resulting from statutory reclassifications" by providing a one-time appeal process for hospitals whose wage index was at least 10 percent less than the wage index of hospitals located in an adjacent MSA that was reclassified by statute.[8] The Proposed Rule lists TWH's current wage index as 11 percent less than the wage indices of its competitor rural hospitals which have benefited from reclassification. Accordingly, based on CMS's prior determinations of the type of hospitals that should receive special treatment, TWH is justified in receiving special treatment under the wage index.

In addition, in rendering decisions on requests for reclassification, The Medicare Geographical Classification Review Board is required to consider information provided by a hospital applicant with respect to the effects of a hospital's geographic classification on access to inpatient hospital services of Medicare beneficiaries. As explained in the bullet below, unless TWH is able to reclassify, there will be a negative impact on access to inpatient hospital services for Medicare beneficiaries. Accordingly, CMS must level the playing field and provide TWH with fair treatment under the wage index by permitting it to reclassify to the same area where its competitors are located/have been reclassified.

- In evaluating Medicare discharges from FY 2005 HCRIS data, 52% of the total Medicare discharges within a 35 mile radius of TWH have received the benefit of increased Medicare reimbursement due to the wage index reclassification of the respective hospitals treating those discharges. This leaves TWH with having to support 31% of the total Medicare discharges in the 35 mile radius without the benefit of increased reimbursement due to wage index reclassification.

3. Why should a hospital be allowed to reclassify to a labor market area that is further away than other, closer urban labor market areas?

As explained above, CMS has stated that geographic reclassification should be limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are "located" (physically located or located by reason of being reclassified) in the geographic area to which they seek reclassification. The focus is on *competition*, not location per se. As explained above, the hospitals with which TWH competes (Geisinger and Evangelical) are within 35 miles of TWH as indicated on the map attached at Exhibit 1, but have been reclassified into the Harrisburg MSA. As also explained above, TWH's competitor hospitals are weakening its effectiveness as a health care provider and market participant. Accordingly, the Harrisburg MSA is the appropriate MSA into which TWH should be reclassified.

Permitting a hospital to reclassify to a labor market area that is further away than other closer urban labor market areas is supported by the fact that individual hospitals[9] which are seeking to reclassify to another area are not required to reclassify to the *closest* urban or rural area to the hospital seeking reclassification. As long as they meet the proximity criteria described in Section 412.230(b), they may reclassify into whatever area they choose.

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[8] See 69 Federal Register 7340, at 7342-3.

[9] With the exception of sole community hospitals and rural referral centers.

Theoretically, a large urban hospital such as TWH that is surrounded by rural hospitals with whom it competes would typically have a higher wage index and a higher average hourly wage than the rural hospitals that surround it. Under these circumstances, one would assume that the rural hospitals surrounding this hospital would seek to reclassify into the closest urban area where its competitor is located. In reality, Geisinger and Evangelical, the rural hospitals surrounding TWH requested and were granted reclassification into the Harrisburg MSA which is located further away than the closer Williamsport MSA, but receives a higher wage index than the Williamsport MSA. These unique circumstances place TWH at a competitive disadvantage which justifies permitting TWH to reclassify to the same MSA where its competitors have been reclassified.

Reclassifying TWH into a closer MSA such as the Scranton-Wilkes-Barre or State College MSA would not be appropriate because: (1) hospitals in these MSAs are not TWH's competitors; (2) historically, these MSAs have had wage indices that have been virtually identical to TWH's[10] and therefore, reclassification into these MSAs would not remedy TWH's disadvantaged status; and (3) while the boundaries of these MSAs may be closer than the boundaries of the Harrisburg MSA, from a market based perspective, TWH competes for staff and patients with, and provides services that exceed or are comparable to the services offered by, Geisinger and Evangelical, both of which have been reclassified into the Harrisburg MSA.

TWH competes for employees with a number of hospitals, but is the only one of these hospitals that does not receive increased reimbursement. TWH has only been able to remain viable and continue to compete with it competitors in the level of services it provides as a result of the efficiencies TWH achieved through its affiliation with SHS in 1994. Now, with no additional costs left to cut and TWH's competitors continuing to receive higher wage indices, TWH is at an unfair competitive disadvantage which will adversely impact the services that TWH is able to provide the community. If TWH is not reclassified into the Harrisburg MSA, TWH will not be able to retain its employees and patient care and access to care will be adversely affected.

Proposed Regulatory Language (proposed language appears in **boldface**)

412.234 Criteria for all hospitals in an urban county seeking redesignation to another urban area.

(a) *General criteria.* For all prospective payment hospitals in an urban county, **except as provided in paragraph (a)(5),** to be redesignated to another urban area, the following conditions must be met:

(1) All hospitals in an urban county must apply for redesignation as a group.

(2) The county in which the hospitals are located must be adjacent to the urban area to which they seek redesignation.

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[10] Since FY 2001, the wage index for the Scranton-Wiles-Barre MSA and the State College MSA have been negligibly lower/higher (2-4%) than TWH's wage index.

(3) (i) For Federal fiscal years before fiscal year 2006, the counties in which the hospitals are located must be part of the Consolidated Metropolitan Statistical Area (CMSA) that includes the urban area to which they seek redesignation.

(ii) For fiscal year 2006, hospitals located in counties that are in the same Consolidated Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation; or in the same Consolidated Metropolitan Statistical Area (CMSA) (under the standards published by the OMB on March 30, 1990) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

(iii) For Federal fiscal year 2007 and thereafter, hospitals located in counties that are in the same Consolidated Statistical Area (CSA) (under the MSA definitions announced by the OMB on June 6, 2003) as the urban area to which they seek redesignation qualify as meeting the proximity requirement for reclassification to the urban area to which they seek redesignation.

(4) The hospital may be redesignated only if one of the following conditions is met:

(i) The prereclassified average hourly wage for the area to which they seek redesignation is higher than the prereclassified average hourly wage for the area in which they are currently located.

(ii) For fiscal years prior to fiscal year 2005, the standardized amount for the area to which they seek redesignation is higher than the standardized amount for the area in which they are located.

(5) Hospital Located in a Single-Hospital MSA Surrounded by Rural Counties Exception. The requirements of Paragraphs (a)(1), (a)(2) and (a)(3) of this section do not apply if the hospital seeking redesignation meets the following criteria:

(i) The hospital is the only hospital in its urban area.

(ii) The hospital is in an urban area that is not adjacent to any other urban area.

(iii) The hospital is seeking redesignation to the closest urban area which is part of a CSA located in the same state as the hospital.

(b) *Wage criteria.* In applying the following numeric criteria, rounding of numbers to meet the qualifying percentages is not permitted.

(1) *Aggregate hourly wage.* The aggregate average hourly wage of all hospitals in the urban county must be at least 85 percent of the average hospital hourly wage in the MSA to which the hospitals in the county seek reclassification; or

(2) *Aggregate hourly wage weighted for occupational mix.* For redesignations effective before fiscal year 1999, the aggregate average hourly wage for all hospitals in the county, weighted for occupational categories, is at least 90 percent of the average hourly wage in the adjacent urban

area.

(c) *Appropriate wage data.* The hospitals must submit appropriate wage data as provided for in §412.230(d)(2).

We thank you for the opportunity to express our comments to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications" and appreciate your consideration of the issues we raised. As always, we would welcome the opportunity to discuss with you in more detail the special circumstances facing Isolated Hospitals in Single-Hospital MSAs and the advocated changes to the Medicare rules allowing for the reclassification of these hospitals.

Sincerely,

Steven P. Johnson, President/CEO
The Williamsport Hospital & Medical Center

cc: Rick Santorum, United States Senator, Pennsylvania
Arlen Specter, United States Senator, Pennsylvania
John Peterson, United States Representative, 5th District of Pennsylvania
Don Sherwood, United States Representative, 10th District of Pennsylvania

EXHIBIT 1


35
Miles
35
Miles

EXHIBIT 2

SERVICE CONTRAST CHART

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Regional Rural Health Partnership Initiative	Yes	Yes	No	No	No	No
Trauma Center and Emergency Department	Level III Eligible	Yes	No	No	No	No
Infectious Disease Center	Yes	Yes	No	No	No	No
Regional IT Infrastructure and Connectivity Among Hospital Facilities and Health System Physicians	Yes	Yes	No	No	No	No
Comprehensive Electronic Medical Record/Lifetime Clinical Record	Yes	Yes	No	No	No	No
Regional Pharmacy Center ° Supporting 5 Hospitals	Yes	No	No	No	No	No
Comprehensive Community Cancer Center (Accredited)	Yes	Yes	No	No	No	No
Comprehensive Wellness & Health Promotion Center ° LifeCenter	Yes	No	No	No	No	No

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Comprehensive Physical Medicine and Rehabilitation Services (CARF Accredited)	Yes	Yes	No	No	No	No
Comprehensive Stroke Center	Yes	Yes	No	No	No	No
Inpatient Dialysis Center	Yes	Yes	No	No	No	No
Cardiac Surgery	Yes	Yes	No	No	No	Yes
Cardiac Catheterizations	Yes	Yes	No	No	Yes	Yes
Cardiac Angioplasty	Yes	Yes	No	No	No	Yes
Comprehensive Neuroscience Center ° Neurosurgery Services	Yes	Yes	No	No	No	Yes
Family Center for Reproductive Health ° Family Planning Center	Yes (including a Family Planning Center)	Yes (without a Family Planning Center)	No	No	Yes	No
Thoracic Surgery	Yes	Yes	No	No	Yes	Yes
Vascular Surgery	Yes	Yes	Yes	No	Yes	Yes
Palliative Care Program	Yes	Yes	Yes	No	No	No
Comprehensive Pain Management Center	Yes	Yes	No	No	No	No

14

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Certified Pastoral Education	Yes	Yes	No	No	No	No
PET Scanning/PET CT Fusion	Yes	Yes	Yes	No	No	No
Emergency Ambulance Services	Yes	Yes	Yes	No	No	No
JCAHO Accreditation	Yes	Yes	No	No	Yes	Yes
Comprehensive Referral Laboratory Services	Yes	Yes	No	No	No	No
Comprehensive CME Program	Yes	Yes	No	No	No	Yes
County Forensics Center	Yes	No	No	No	No	No
Diabetes Resource Center	Yes	Yes	No	No	No	Yes
Hyperbaric Chamber Care	Yes	No	No	No	No	No
Helicopter Services	No	Yes	No	No	No	No
NICU	No	Yes	No	No	No	No
Family Practice Residency Training Program	Yes	No	No	No	No	No
Other Physician Residency Training Programs	No	Yes	No	No	No	No
Transplant Services	No	Yes	No	No	No	No

EXHIBIT 3

COMPARISON OF NORTH CENTRAL PA HOSPITALS
EMERGENCY ROOM CAPABILITY AND VOLUME

Updated: 3/28/2006

PROVIDER NUMBER	NAME	COUNTY	EMERGENCY CAPABILITY	TOTAL VISITS	E.D. INPATIENT ADMITS	AMBULANCE SERVICE				
						ALS	BLS	AIR	MICU	MCCU
390045	Williamsport Hospital	Lycoming	Comprehensive	50,874	6,282	Yes	Yes	No	Yes	No
390013	Evangelical Hospital	Union	General	28,049	3,849	Yes	Yes	No	No	No
390006	Geisinger Medical Ctr.	Montour	Comprehensive	37,246	6,161	No	No	Yes	No	No
390079	Robert Packer Hospital	Bradford	General	28,182	4,660	No	No	No	No	No
390071	Lock Haven Hospital	Clinton	General	12,773	1,700	Yes	No	No	No	No
390043	Soldiers & Sailors Hosp.	Tioga	General	14,429	1,600	Yes	Yes	No	Yes	No
390246	Charles Cole	Potter	General	9,265	1,348	Yes	No	No	No	No
390072	Berwick Hospital	Columbia	General	13,634	1,968	No	No	No	No	No
390003	Bloomsburg Hospital	Columbia	General	14,086	1,538	No	No	No	No	No
390268	Mt. Nittany Medical Ctr.	Centre	General	40,870	5,229	No	No	No	No	No
Harrisburg Area Hospitals										
390004	Holy Spirit Hospital	Cumberland	General	50,375	9,488	Yes	Yes	No	Yes	No
390256	Hershey Medical Ctr.	Dauphin	Comprehensive	45,044	7,656	Yes	Yes	Yes	No	No
390067	Pinnacle Hospitals	Dauphin	General	78,274	14,157	Yes	No	No	No	No

Source Dept of Health, Annual Hospital Questionnaire - July 1, 2003 through June 30, 2004

Abbreviations:

ALS - Advanced Life Support BLS - Basic Life Support AIR - Air Ambulance
MICU - Mobile Intensive Care Unit MCCU - Mobile Critical Care Unit

EXHIBIT 4

COMPARISON OF NORTH CENTRAL PA HOSPITALS
CASE MIX, WAGE INDEX AND AVERAGE HOURLY WAGE

Updated: 5/15/2006

PROVIDER NUMBER	NAME	COUNTY	CASE MIX INDEX	WAGE INDEX FY2007		AVER. HRLY WAGE FY2005	AVER. HRLY WAGE FY2006	AVER. HRLY WAGE FY2007	3-YEAR AHW FY2007
390045	Williamsport Hospital	Lycoming	1.6290	0.8330		$22.2582	$23.0712	24.0257	23.1327
390013	Evangelical Hospital	Union	1.2264	0.9263	1	23.3180	24.0044	24.9820	24.0935
390006	Geisinger Medical Ctr.	Montour	1.8717	0.9263	1	23.3960	25.1216	26.9964	25.2038
390079	Robert Packer Hospital	Bradford	1.8657	0.8499	1	21.4323	23.3053	22.3152	22.3289
390071	Lock Haven Hospital	Clinton	0.9947	0.8330	1	20.9443	21.8366	25.0434	22.4830
390043	Soldiers & Sailors Hosp.	Tioga	1.2148	0.8330	3	20.9835	22.2549	23.4652	22.2302
390246	Charles Cole	Potter	1.1657	0.8330	3	23.3275	20.1581	25.5357	22.7908
390072	Berwick Hospital	Columbia	1.0662	0.9927	2	22.0155	24.9388	24.8220	23.8819
390003	Bloomsburg Hospital	Columbia	1.1504	0.9927	2	21.3182	21.6478	23.1149	22.0126
390268	Mt. Nittany Medical Center	Centre	1.3621	0.8804		24.2050	25.0021	26.0621	25.1256
390279	Philipsburg Area Hospital	Centre	1.1033			15.3569	17.0012		16.1698
Harrisburg Area Hospitals									
	Holy Spirit Hospital	Cumberland	1.6415	0.9413		23.4063	24.3249	24.8914	24.2683
390256	Hershey Medical Ctr.	Dauphin	1.8697	0.9413		24.2331	26.3619	28.6363	26.4469
390067	Pinnacle Hospitals	Dauphin	1.8178	0.9413		25.4576	26.3287	28.9773	26.8680

	FY2007 AHW		3-Year AHW		Wage Index		GAF	
Williamsport CBSA	24.0257	4	23.2070	4	0.8330	5	0.8824	5
Harrisburg - Carlisle CBSA	27.8666	4	26.2093	4	0.9263	6	0.9489	6
Difference	3.8409		3.0023		0.0933		0.0665	
Difference - %	16.0%		12.9%		11.2%		7.5%	
Rural - Penna. - by CBSA	24.6593	4	23.2635	4	0.8330	7	0.8824	7

Source: Federal Register, 4/25/2006, Proposed 2007 IPPS Rules, Table 2

Notes:

1. Reclassified per Table 9A of Proposed Rules
2. Reclassified per Table 9B of Proposed Rules - Section 508 Reclassification
3. Hospitals are in rural areas and have qualified for Sole Community Hospital status
4. According to Table 3A, 3B FY2007 Average Hourly Wage and 3-Year Average Hourly Wage by CBSA
5. According to Table 4a, the Wage Index and Capital Geographic Adjustment Factor (GAF) by CBSA
6. According to Table 4C, the Wage Index and Capital Geographic Adjustment Factor (GAF) for Hospitals Reclassified
7. According to Table 4B, the Wage Index and Capital Geographic Adjustement Factor (GAF) for Hospitals in Rural Areas by CBSA
8. Mt. Nittany Medical Center in Centre County was formerly Centre Community Hospital

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NORTH AMERICAN PRIMARY CARE RESEARCH GROUP
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www.napcrg.org

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: **CMS-1488—P "Resident Time in Patient-Related Activities"**

Dear Administrator McClellan:

On behalf of the five family medicine organizations we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge CMS to rescind the language in the proposed rule that sets up an artificial dichotomy between resident training time spent in didactic activities and time spent in "patient care activities." The effect of the proposed rule is to exclude medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Misinterpretation of Legislative History

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position reverses the Agency's position expressed as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We support the Agency's 1999 position. The activities cited in the 1999 letter and cited again in this proposal are an integral component of the patient care activities engaged in by residents during their residency programs. Although the proposal states that this 1999 position was incorrect; we believe CMS's current interpretation is the incorrect one, and we wonder why CMS feels the need to change its position in this matter.

There also is no specific reference to patient care activities in the hospital setting in the IME legislation. CMS's position refers to unrelated policy that is regulatory in nature (42 CFR 413.9), not statutory. We disagree with the use of this regulation as a basis for this proposal.

If one looks at the legislative history of Medicare, one finds a different interpretation than the one CMS cites. The House Ways and Means and Senate Finance Committee Reports, in March 1983 – state the purpose of the Indirect Graduate Medical Education (IME) as "This adjustment is provided in light of doubts...about the ability of the DRG case classification system to account fully for factors such as severity of illness of patients requiring the specialized services and treatment programs provided by teaching institutions **and the additional costs associated with the teaching of residents** [emphasis added]...the adjustment for indirect medical education costs is only a proxy to account for **a number of factors which may legitimately increase costs in teaching hospitals**.[emphasis added]" As such, the language in the federal register proposal defining the "plain meaning" of patient care as related to the care and treatment of a specific patient or to services for which physicians can bill, is patently incorrect.

Congress's position with respect to the non-hospital setting is just as clear regarding IME payments. The conference agreement language accompanying the legislative language from the BBA states "The conference agreement includes new permission for hospitals to rotate residents through non-hospital settings, which include primarily ambulatory care settings, **without reduction in indirect medical education funds.**" (emphasis added)

It seems to us that the only piece of this proposal that CMS has any potential standing relates to the question of payment of DGME and IME in the nonhospital setting. On that issue, we believe that CMS's position is also incorrect, not because they are wrong in citing what the statute states, but because of their interpretation of that position. CMS, in this regard, is relying on artificial dichotomies between didactic and patient care training time to make a false case for carving out didactic training in the nonhospital setting from the DGME and IME payments. Again, we believe the "plain meaning" of patient care activities as defined in this proposal is erroneous.

Residency Program Activities and Patient Care

We firmly believe that with the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of fully-trained physicians. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

Here are several examples from actual residency training programs in family medicine of how training in residency programs relates to patient care – no matter the format of the teaching/learning:

- Each of my residency sites ends the day with an hour-long session in the conference room called "chart rounds." The session is a teaching conference for the residents at the Family Health Center for that afternoon, based on the patient care that was delivered over the past 3-4 hours. It also provides a second opportunity for the preceptor to review the care that was just given; occasionally the group discussion will recommend a different approach, another test, etc. and a resident may call the patient back, etc. First year residents are required to present all cases, PGY-2 and 3 focus on cases that are challenging, illustrative, etc. Sometimes earlier in the afternoon the preceptor will deal with a difficult question about a patient by saying "hold that until chart rounds so we can do it justice." Is this didactic teaching, or patient care?

- We run resident Balint Groups. The discussion is devoted to working through difficult doctor-patient interactions, helping the resident to better understand and approach these relationships. They are based on real cases, and hopefully lead to better care. Didactic teaching, or patient care?

- Almost all residency teaching opens with a patient case. Even if the case does not come from the residency practice, the material in the teaching sessions is applied directly to patient care in that practice, often immediately. Didactic teaching, or patient care?

- Many teaching sessions actually physically include a patient in the presentation. The patient might be interviewed or examined in front of the learners. Didactic teaching or patient care?

- Many teaching sessions involve skills practice, e.g. interviewing skills. Some times patients are even asked to attend the teaching sessions so that faculty (or trainees) can demonstrate physical findings (e.g. neurologic or orthopedic) or procedures (e.g. soft tissue injection) for the attendees. Didactic teaching or patient care?

- Journal clubs often discuss particular patient cases from the practice (de-identified) as examples or illustrations of issues discussed in the journal article. A common mode of speech among physicians both during and after training is "I had this patient once...." and then the educational discussion ensues. Didactic teaching or patient care?

- In most programs I know about current clinical cases in the hospital often form the basis for Grand Rounds and Case Conferences. These conferences frequently come up with expert opinions and well-researched ideas that contribute positively to those patients' care, providing patients in the hospital a real-time benefit from the teaching conferences. Didactic training or patient care?

- Scholarship is required for residency training by the accrediting RRC for family medicine. POEMS/FPIN Clinical inquiries are the basis of many scholarly activities within residency training. They start and end with clinical questions drawn from actual cases/practices, discuss the best evidence in answering them, along with how to integrate that into patient care in practical terms. Didactic training or patient care?

- Interns in our family medicine program attend a series of Friday afternoon "survival skills" presentations for the first 3 months of their intern year. These presentations involve case based learning with the objectives covering essential skills in managing medical emergencies that the interns may well encounter when on call. Topics include such things as acute coronary syndrome, congestive heart failure, renal failure, electrolyte imbalances, intubation and ventilator management protocols. While the interns have certainly encountered all of these topics in their medical school experiences, the consistency of the group's knowledge base, and the level of responsibility they have had in caring for such problems, is not predictable. If, as a program, we failed to address these topics to prepare our interns, we would be ignoring potentially critical patient safety concerns. These presentations are essential additions to the hands-on clinical learning experiences offered to our residents. Didactic training or patient care?

The underlying premise of residency training is that medical students do not graduate with all the skills and knowledge needed to be practicing physicians -- that is why they are required to learn as residents. All of the knowledge and skills for safe patient care cannot be transmitted with hands on learning. There is specific didactic curricular content (as required by each specialty RRC) that prepares the resident physicians for the next stage of patient care responsibility, with less supervision expected and required as the resident progresses through his or her training.

Having this teaching time funded is essential to maintaining patient safety in the learning environment. Learners have to have teaching sessions where they can talk about cases and how to care for patients safely. To use the metaphor of the IOM report on safety and errors in medicine, not funding teaching time would only add to the "jumbo jet worth of patients crashing" each day from medical errors.

Consistency of Logic

One additional issue that we would like CMS to consider relates to the lack of logical coherence of its positions. For example, on the one hand CMS argues that in order for hospitals to receive DGME and IME payments for residents training in non hospital settings the hospital must pay supervising physicians the costs associated with the time they spend educating residents in activities not associated with direct hands on patient care. And yet, under this proposal the hospital would not be able to claim any time in the non-hospital setting unless it was time spent "in the care and treatment of specific patients

As shown above, we believe all teaching time to be related to patient care. Irrespective of your position on whether preceptors can volunteer that teaching time, it is clear to us that CMS cannot on the one hand say the hospital needs to pay those costs, and on the other say that those costs can't be included in the cost reports.

Regulatory Burden/Impracticability

We cannot conceive of how programs would be able to administratively comply with this requirement. It would require documentation that would be extremely burdensome, if possible at all. To separate out CMS's newly defined "patient care time" from didactic sessions in which general issues devolve to discussions of particular patients seems an exercise in futility. Even if it could be done, where would the funding come from to pay for the staff person or two that would be needed to sit in on each of these didactic sessions and keep count of patient care time? The documentation requirements that this position would necessitate are unreasonable and would cause an extremely large administrative burden, assuming one could even meet the requirements.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to patient care experiences of residents during their residency training.

Sincerely,

Caryl Heaton, DO, President
Society of Teachers of Family Medicine

Mary Frank, MD, President
American Academy of Family Physicians

Sam Jones, MD, President
Association of Family Medicine Residency Directors

Warren Newton, MD, President
Association of Departments of Family Medicine

Perry Dickinson, MD, President
North American Primary Care Research Group

Beebe Medical Center

June 9, 2006

VIA FEDERAL EXPRESS

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: "**Hospital Redesignations and Reclassifications**" and "**Provider missing from Table 9A**."

Dear Sir/ Madam:

These comments relate to the Section III.H.6 of the proposed rule regarding "Proposed Wage Indices for Reclassified Hospitals and Proposed Reclassification Budget Neutrality Factor" and to point out that Beebe Medical Center (BMC-080007) is erroneously not listed as being reclassified to Ocean City, NJ (36140) on Table 9A of the proposed rule. A copy of the Medicare Geographic Classification Review Board approval letter is attached for your reference.

"Hospital Redesignations and Reclassifications"

Beebe Medical Center (BMC) (08-0007) is a 133-bed acute care hospital located in Lewes, Delaware. The hospital is also a rural referral center. The hospital provides a broad array of services to the citizens of Sussex County, Delaware and surrounding adjacent areas. The hospital is a referral center, an according, provides services to areas to its north, south, east and west. As such it also competes for skilled labor with the surrounding adjacent areas.

Because of the referral nature of its business, BMC competes for labor with other referral centers in Delaware, some as far away as Wilmington, Delaware. To its south are the hospitals in Maryland, which has a unique hospital payment system that provides payments to those hospitals that are approximately $16.0 million more than if those

hospitals were under the same payment system as BMC. Another competitor hospital in Delaware to BMCs north is reclassified to the Wilmington CBSA/MSA. BMC is reclassified to the adjacent area of Ocean City NJ CBSA/MSA, which receives the New Jersey rural floor but BMC does not receive that rural floor AWI. This creates a situation where BMC is paid less than surrounding referral hospitals with whom it competes for labor. Therefore, because of the various labor adjustments of competing area hospitals, BMC is disadvantaged in the situation for attracting labor. This situation appears to be somewhat unique when hospitals are adjacent to and reclassify to areas that receive the rural floor AWI.

The solution to this payment disparity appears be to pay hospitals that reclassify into an area that is subject to the rural floor AWI, the rural floor of the area into which it is reclassified.

The process for geographic reclassification was created by Congress with the intention of allowing a hospital the opportunity to be able to reclassify to a different area. Presumably, this would afford the hospital the opportunity to be paid based upon the AWI of that other area. CMS in developing its reclassification rules included a proximity and adjacency criteria. These were included to allow a hospital that is proximate to an adjacent area to reclassify to that area subject to other wage comparability tests. In the application of these reclassifications CMS' present policy does not provide the reclassified hospitals in certain circumstances to receive an AWI that is comparable to the hospitals in the area into which it was reclassified. This is particularly the case in the situation of the rural floor. In these situations the reclassified hospital receives an AWI that is often dramatically different than the AWI of the adjacent area into which the hospital was reclassified. This appears to be counter to what congress intended in establishing the reclassification process. Accordingly, the appropriate remedy seems to be, as suggested previously, that in the case of hospitals reclassifying to an area that is subject to the rural floor such hospitals should receive that rural floor as its AWI.

CMS has the authority to make this type of change and has used this authority to address labor market area issues. The Secretary has broad authority under section 1886(d)(3)(E) of the Social Security Act, which allows the Secretary to make adjustments to reflect area wage differences given the particular labor market situations. CMS relied on this same authority when it established the imputed rural floor for "all urban states." In addition it has used this authority to make labor market adjustments when the new labors markets where put in place. Therefore, CMS has the discretionary authority to make similar adjustments from time to time as it sees appropriate.

Hospital not Listed on Table 9A

BMC (080007) is geographically reclassified to the Ocean City, NJ CBSA/MSA (36140). In the proposed rule for FY 2007, our hospital is not listed as being reclassified to the Ocean City, NJ CBSA/MSA; however, on Table 2 our hospital does correctly have the reclassified AWI listed for hospitals that are reclassified to that area. We request that CMS include our hospital on Table 9A as being reclassified for FY 2007 to the Ocean City, NJ CBSA/MSA.

We appreciate the opportunity to make these comments and hope that you will make the adjustment that we are requesting. If you have any questions about these comments please do not hesitate to contact me at 302-645-3537.

Sincerely,

Jeffrey M. Fried, FACHE
President & CEO

Attachment 135

DEPARTMENT OF HEALTH AND HUMAN SERVICES
MEDICARE GEOGRAPHIC CLASSIFICATION REVIEW BOARD
2520 Lord Baltimore Drive, Suite L
Phone: 410-786-1174 Baltimore MD 21244-2670 FAX: 410-786-5298

FEB 0 2 2006

CERTIFIED MAIL

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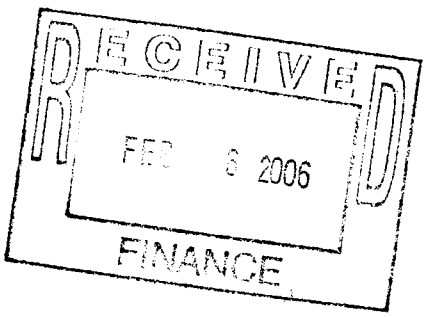

TO: Beebe Medical Center, Inc.
James W. Bartle
Vice President of Finance
424 Savannah Road
Lewes, DE 19958

RE: Beebe Medical Center, Inc.
Provider No. 08-0007
Federal Fiscal Year(s) Beginning – 10/01/06

SUBJECT: Decision - Medicare Geographic Classification Review Board

The Medicare Geographic Classification Review Board (Board) has reviewed the hospital's application for redesignation in accordance with Section 1886(d)(10) of the Social Security Act and 42 C.F.R. § 412.230ff. The Board has considered the facts and the data submitted in support of its application. The Board hereby APPROVES the hospital's request for redesignation for the purpose of using the WAGE INDEX VALUE for the period October 1, 2006 through September 30, 2009. See the attached Case Summary for additional information.

You may appeal this decision to the Administrator of the Centers for Medicare & Medicaid Services. The Office of the Attorney Advisor must receive your request for review no later than 15 days from the date of this notice. You should send your request to the following address:

Centers for Medicare & Medicaid Services
Office of the Attorney Advisor
Room C3-01-20
7500 Security Boulevard
Baltimore, MD 21244-1850

Board Members Participating:
Robert G. Eaton
Harold W. Brown
Rebecca T. Brewer
Martin W. Hoover
Charles R. Barker

For the Board:

Robert G. Eaton
Chairman

cc: Office of the Attorney Advisor, OCOS, OA, CMS
Division of Acute Care, Hospital & Ambulatory Policy Group, CMM, CMS

*NOTE: Please reference case number in all communications.

FEB 0 2 2006

Wage Index Case Summary

Case Number:.....07C0055-1
Provider Name:.....Beebe Medical Center, Inc.
Provider Number:.....08-0007

Hospital's Average Hourly Wage:.....25.0565

Seeking Redesignation From: 08
Rural **DELAWARE**
MSA Average Hourly Wage: 25.1791

Seeking Redesignation To: 36140
Urban **Ocean City, NJ**
MSA Average Hourly Wage: 28.5543

Timely Filed:.....Yes

Sole Community Hospital:.....No

Rural Referral Center:.....Yes

Have you ever been an RRC?:.....Yes

SCH Status Lost Due to Prior MGCRB Reclassification?:.....No

Applying Under Access Rules?:.....No

If SCH/RRC, is Requested Area Closest?:.....N/A

Mileage to County Line:.....17.60

Meets Proximity Criteria [42 CFR 412.230(b)]?:.....Yes

Meets the 106% / 108% Criteria [42 CFR 412.230(d)(1)(iii)(C)]?:.....N/A

Meets the 82% / 84% criteria [42 CFR 412.230(d)(1)(iv)(C)]?:.....Yes
25.0565 / 28.5543 x 100 = **87.7503%**

Meets All Necessary Criteria For Reclassification?:.....Yes

136

Bethesda Memorial Hospital

Overnight Mail Tracking No: 791012406706

June 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Inpatient Prospective Payment Systems and FY 2007 Rates regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications" (File Code CMS-1488-P)

Dear Sir or Madam:

The purpose of this letter is to comment on the FFY 2007 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications.

Our facility is a 390-bed not-for-profit hospital located in Palm Beach County Florida. Forty one percent (41%) of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

In 2004, when the FFY 2005 proposed IPPS regulation regarding geographic wage index reclassifications and urban group hospital reclassifications was published, Palm Beach County hospitals had, for the first time, qualified for the opportunity to reclassify for wage index purposes. Palm Beach County hospitals qualified in part because the FFY 2005 proposed rule allowed Metropolitan Divisions within a CBSA to qualify for an urban group reclassification. Based on the FFY 2005 proposed regulation, we joined with all other Palm Beach County hospitals and applied for the urban group reclassification. However, the final FFY 2005 IPPS regulation revised the proposed criteria and eliminated the ability for Metropolitan Divisions within a CBSA to qualify for an urban group reclassification.

We subsequently learned, however, from CMS through the FFY 2007 IPPS proposed regulation that the intent of the urban group reclassification was, and is, "to allow hospitals located in counties that are in the same CBSA (in the case of Metropolitan Divisions) as the area to which they seek redesignation to be considered to have met the proximity requirement We agree with CMS on the point above and agree with CMS on the following two points; that "the proximity standard for group reclassifications is intended to allow all of a county's hospitals to reclassify to an adjacent area where there is sufficient economic integrations that there can be an expectation that both areas are competing in a similar labor market area," and that "we believe there is sufficient economic integration between Metropolitan Divisions within a CBSA that urban county reclassifications within a CBSA or a CSA should be permitted."

We thank CMS for recognizing the economic integration between Metropolitan Divisions within a CBSA and request that CMS, at a minimum, adopt the FFY 2007 IPPS proposed urban group reclassification eligibility criteria [Sec. 412.234(a)(3)] as proposed, without modification.

However, we do believe, based on the CMS comments quoted above from the FFY 2007 IPPS proposed regulation, that the hospitals of Palm Beach County should have been allowed to qualify for an urban group reclassification beginning in FFY 2006 had the final FFY 2005 IPPS regulations correctly recognized the economic integration between Metropolitan Divisions within a CBSA (as CMS had done in the FFY 2005 proposed regulation and now again recognizes in the FFY 2007 proposed regulation).

Therefore, we respectfully request that CMS, in the final FFY 2007 IPPS regulation, make the FY 2007 proximity criteria effective for urban group reclassifications beginning on October 1, 2006 (as opposed to October 1, 2007) IF the urban area:

- Filed an application for urban group reclassification by September 1, 2004 for reclassification beginning on October 1, 2005;
- Met all of the non–proximity urban group reclassification criteria published in the FFY 2005 final regulation;
- Had the application denied only because the urban area did not meet the flawed FFY 2005 proximity criteria;
- Would have had the application approved had the FFY 2007 proposed proximity criterion been the criterion in the FFY 2005 final regulation;
- Meets the proximity and non-proximity criteria described in the FFY 2007 IPPS proposed regulation; and
- Files an application for urban group reclassification by September 1, 2006.

Based on the aforementioned information we request that CMS incorporate the proposed revision, as written above, in the FFY 2007 final IPPS regulation. We believe the requested revision is critical to the financial stability of the hospitals located in the West Palm Beach Metropolitan Division and should take effect, for payment purposes, for all hospitals in the West Palm Beach Metropolitan Division beginning October 1, 2006 rather than delaying until October 1, 2007. If granted this revision will allow the urban group reclassification to take effect one year sooner than otherwise currently proposed, though a year later than the date which we would have otherwise qualified (October 1, 2005) had the final FFY 2005 regulation properly recognized the intent of the economic integration criteria.

We appreciate your consideration of this comment to the FFY 2007 proposed IPPS regulation.

Sincerely,

Joanne Aquilina
Vice President Finance/CFO

c.c. Mr. Robert B. Hill, President/CEO

137

Susquehanna Health System
Divine Providence Hospital - Muncy Valley Hospital
The Williamsport Hospital & Medical Center

Richard W. DeWald
Chairman of the Board

Sister Joanne Bednar
Vice Chairman

Steven P. Johnson
President & CEO

June 9, 2006

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Published in the Federal Register on April 25, 2006

To Whom It May Concern:

Geographic Reclassifications

The following comments are being submitted on behalf of The Susquehanna Health System (SHS) relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule (the "Proposed Rule") titled "Geographic Reclassifications." Located in north central Pennsylvania, SHS was formed in 1994 by two formerly competing health systems. SHS is the largest employer in Lycoming County and serves as an economic cornerstone for the region, providing nearly $337 million to the region's economy and employing over 3,000 employees with an annual payroll of $119 million. In addition to the 120,000 Lycoming County citizens, SHS functions as a regional referral enter for seven additional hospitals and an additional 400,000 residents in the 10 surrounding counties. In the first five years of the merger, SHS operating efficiencies resulted in documented savings of $105 million to the Community. SHS's contributions to charity services, community health programs and subsidized patient are total over $35 million for 2004 alone.

One of the hospitals in the SHS, The Williamsport Hospital (TWH) is in crisis because it is the only major hospital in an 11 county region that is not receiving special reimbursement under current wage index payment rules of the Medicare Program. SHS has had to divert capital funds to pay wages, delaying investment in necessary patient care technology and threatening the continued development of the extensive patient information technology system. The Centers for Medicare & Medicaid Services ("CMS") has acknowledged the problem on several occasions and now has the opportunity to solve it. SHS strongly supports the advocated changes to the Medicare rules allowing for the reclassification of hospitals located in a single hospital MSAs

surrounded by rural counties. CMS should immediately adopt these changes to the urban county group reclassification regulations whereby a hospital in a single hospital MSA surrounded by rural counties would be able to reclassify to the closest urban area that is part of a Combined Statistical Area ("CSA") located in the same State as the hospital.

In what we believe is only two areas of the United States today, there are individual urban hospitals[1] that are the sole hospital in their particular urban area (hospitals in single-hospital MSAs) that have historically found themselves surrounded by rural hospitals with whom they compete that receive higher Medicare payments because they have been reclassified to higher Medicare wage index areas or because CMS considers them rural referral centers, sole community hospitals, critical access hospitals or Medicare dependent hospitals (we will hereinafter refer to these hospitals as "hospitals located in a Single-Hospital MSA surrounded by rural counties").[2] Because these hospitals located in a Single-Hospital MSA surrounded by rural counties operate in urban areas that are not adjacent to any other urban area, they are unable to secure Medicare wage reclassification although they are at a competitive disadvantage because they are competing for labor with hospitals in nearby areas with higher wage indices. They cannot secure Medicare wage reclassification on an individual hospital basis under 42 CFR 412.230 because, according to CMS standards, they are too far from the nearest urban area[3] and, by definition, the ratio of a hospital in a single-hospital MSA's average hourly wage to the average hourly wage of hospitals in the area in which the hospital is located is always 100% and therefore, these hospitals can not meet the 108% threshold for urban hospitals. Similarly, these unique hospitals cannot secure Medicare wage reclassification on a county-wide basis under 42 CFR 412.234 because they are not adjacent to any urban area, for fiscal year 2007, are not part of a consolidated metropolitan statistical area ("CMSA") or combined statistical area ("CSA") that includes the urban area to which they seek redesignation, and for fiscal years 2008 and thereafter, are not part of a CSA that includes the urban area to which they seek redesignation.

Despite the fact that CMS has specifically stated that geographic reclassification is for hospitals that are disadvantaged by their current classification because they compete with hospitals that are located in the geographic area to which they seek reclassification,[4] and that the intent for its FY 2006 proposed changes to the urban group hospital reclassification criteria was "to preserve the reclassification opportunities for urban county groups,"[5] we believe CMS has failed to adequately address the inequities facing a specific subset of urban county groups, namely hospitals located in a Single-Hospital MSA surrounded by rural counties, in relation to the wage index and the rules governing geographic reclassification and is therefore failing to preserve the reclassification opportunities for <u>all</u> urban county groups. The advocated changes

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[1] Unless specified otherwise, the use of the term "hospital" or "hospitals" in this comment letter only refers to hospitals reimbursed under the prospective payment system.

[2] From our research, it appears that only TWH, located in Williamsport, Pennsylvania, Lycoming County (Williamsport, PA MSA) and Community Hospital, located in Grand Junction, Colorado, Mesa County (Grand Junction, CO MSA) meet the definition of hospitals located in a Single-Hospital MSA surrounded by rural counties.

[3] Urban hospitals must be within 15 miles of the urban area into which they seek reclassification for Medicare wage purposes. (Rural hospitals are permitted to be within 35 miles of the area to which they seek reclassification).

[4] June 4, 1991 Final Rule - 56 FR 25469; See also June 2, 1995 Proposed Rule – 60 FR 29202.

[5] May 4, 2005 Federal Register.

described in the Proposed Rule will enable CMS to adequately preserve the reclassification opportunities for urban county groups.

The Proposed Rule invited comments on three specific questions concerning the reclassification for hospitals located in a Single-Hospital MSA surrounded by rural counties.

1. What is the justification for reclassifying a hospital that is receiving a wage index reflecting its own wages?

A hospital, such as TWH, that receives a wage index reflecting its own wages is justified in seeking reclassification when its competitors have all been reclassified to and/or are located in an area that receives a wage index reimbursement that is significantly higher than the competitors' actual wages. The geographic reclassification rules have created an anomaly whereby a reclassified hospital may receive wage index reimbursement above its own average hourly wage. This excess reimbursement allows these reclassified hospitals to choose between raising employees salaries or investing in new technology and services. The disadvantage for the hospital receiving a wage index reflecting its own wages that competes with the reclassified hospitals is that it must continually work to keep wages competitive while struggling to purchase new technology and continue to provide the services the Medicare beneficiaries in its community need.

Set forth below are specific examples of why TWH is justified in being reclassified despite receiving its own wage index, including an analysis of TWH's competitors and specific examples of how patient care and access to care will be adversely affected if TWH is not reclassified into the same MSA where its competitors are located and/or have been reclassified.

- TWH's competitor hospitals (in terms of proximity, comparability of services and other factors relevant to geographic reclassification) are Geisinger Medical Center ("Geisinger") and Evangelical Community Hospital ("Evangelical"), both of which have been reclassified into the Harrisburg MSA and thereby receive a higher wage index than TWH, placing TWH at a competitive disadvantage.

  - As shown on the map attached at Exhibit 1, Geisinger and Evangelical are the only PPS hospitals with which TWH competes that are located within 35 miles of TWH. Both Geisinger and Evangelical frequently use billboard, newspaper and radio advertising in Williamsport to recruit patients and staff to their facilities.

  - As shown on the Service Contrast Chart attached at Exhibit 2, the level of services TWH provides is close to that provided by Geisinger and substantially more than that provided by Evangelical. As also shown on the Service Contrast Chart, the level of services TWH provides is similar to that provided by Holy Spirit Hospital which is located in the Harrisburg MSA; and greater than that provided by Lock Haven Hospital, a rural hospital, and Mt. Nittany Hospital which is located in the State College MSA.

  - As shown on the Emergency Room Capability and Volume Chart attached at Exhibit 3, TWH has a significantly larger volume of emergency room visits than

all the other hospitals in the region. TWH's volume of emergency room visits is comparable to the volume of emergency room visits of the hospitals located in the Harrisburg MSA, whereas the volume of Geisinger's and Evangelical's emergency room visits is substantially less than the volume of emergency room visits of the hospitals located in the Harrisburg MSA even though Geisinger and Evangelical have been reclassified into the Harrisburg MSA.

- As shown on the Comparison of North Central PA Hospitals Chart attached at Exhibit 4, TWH's case/mix index is comparable to the case/mix index of the hospitals that are physically located in the Harrisburg MSA and/or have been reclassified into the Harrisburg MSA (e.g., Geisinger) and is notably more acute than the remaining hospitals in the region.

- Historically, TWH's base salary for entry level nurses was comparable to Geisinger's. However, Geisinger is currently able to offer a higher base salary for entry level nurses, a higher signing bonus for nurses[6] and a recent 12% increase in nurse salaries due to the fact that it receives a higher wage index than TWH. TWH's ability to recruit and retain nurses is negatively affected by its inability to offer similar benefits as a result of its receiving a lower wage index. In the long run, this makes it difficult, if not impossible, for hospitals located in a Single-Hospital MSA surrounded by rural counties to recruit and retain the qualified health care professionals they need to serve their communities. This concern is especially significant given the fact that TWH is the only hospital in its urban area and therefore has an even greater obligation to the communities they serve. Without necessary assistance from CMS, the long term financial viability of TWH is questionable.

- For the first time in five years, TWH experienced a significant reduction in its employees' job satisfaction as a result of TWH's inability to provide competitive wages and benefits, as evidenced by a recent internal employee opinion survey.

- TWH has only been able to remain viable and continue to compete with Geisinger and Evangelical in the level of services it provides as a result of the efficiencies TWH achieved through its affiliation (the "Affiliation") with Susquehanna Health System ("SHS") in 1994.[7] These efficiencies were implemented over a 10-year period

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[6] Geisinger is able to offer a signing bonus equal to $4,000 - $5,500 depending on the individual's willingness to work nights and weekends. TWH is only able to offer a $2,000 signing bonus.

[7] Prior to 1994, TWH and its health care affiliates operated as an independent health care system in the Williamsport area known as North Central Pennsylvania Health System ("NCPHS"). At the same time, inpatient and outpatient hospital and other medical services were also provided in the same area by Divine Providence Hospital of the Sisters of Christian Charity ("Divine Providence Hospital"), Muncy Valley Hospital and their affiliates as an independent health care system in the Williamsport area known as Providence Health Foundation ("PHF"). In 1994, the PHF and NCPHS systems, including Divine Providence, Muncy Hospital and TWH, combined their operations having concluded that the effective delivery of high quality, cost effective health care in North Central Pennsylvania required the integration of their operations. The combination was effectuated through the organization of Susquehanna Regional Health Care Alliance (which operates as SHS) and the

ending in 2004. Major cost reduction efforts included a 30% reduction in TWH's bed complement from 325 licensed beds to 225, and consolidation/reduction of administrative overhead and support services. In addition, of the 282 licensed beds at SHS's other two hospitals (Divine Providence Hospital and Muncy Valley Hospital) 80% or 226 beds were delicensed. As a result, the overall SHS licensed acute bed complement decreased from 607 to 325 or a 54% reduction. Now, with no additional costs left to cut and TWH's competitors continuing to receive higher wage indices, TWH is at a competitive disadvantage which will adversely impact the services that TWH is able to provide the community. While one might suggest that in a market place environment those hospitals with higher labor reimbursements may, in the future, offer additional or expanded services especially when TWH is forced to curtail them, convenient access to these services by less ambulatory seniors will be lost.

- If TWH is not reclassified into the Harrisburg MSA, TWH will not be able to retain its employees and patient care and access to care will be adversely affected as TWH is no longer able to make up the shortfall through any additional cost reduction efforts because it has already achieved a high level of efficiency as a result of the Affiliation. Based on calculations by an auditor engaged by the Pennsylvania Attorney General, SHS realized a net cost savings of $105 million dollars as a result of the Affiliation, yet SHS gave back 117% of its savings to the community in the form of low-cost or no-cost health care programs for the community, reduction in prices and/or limiting actual price increases for existing services, although it was only required by the Pennsylvania Attorney General to return 80% of the net cost savings it achieved as a result of the Affiliation to the community.

- Based on the fact that TWH's top competitors are Geisinger and Evangelical, both of which have been reclassified into the Harrisburg MSA, TWH has clearly demonstrated an economic connection to the Harrisburg MSA.

- TWH is a member of the Susquehanna Valley Rural Health Partnership ("SVRHP") a three-county rural health network of which TWH is the network referral facility. In this capacity, TWH supports a number of hospitals and a federally qualified health care center ("FQHC") including Muncy Valley Hospital, Bucktail Medical Center, Jersey Shore Hospital and Laurel Health which owns and operates the FQHC. If TWH is not reclassified into the Harrisburg MSA, TWH may no longer be able to support these health care organizations by providing IT services, hospital pharmacy services, medical transport services and physician continuing medical education programs.

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delegation to SHS of responsibility for overall management and operation of the hospitals and their health care affiliates.

2. Why should a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals that have received one form or another of special payment status relating to their rural locations, receive special treatment under the wage index?

A hospital should receive special treatment under the wage index when it is a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals ***with whom it competes*** (in terms of services provided, emergency room visits and case/mix) that have received one form or another of special payment status relating to their rural locations. Under these circumstances, the wage index reclassification rules interfere with a competitive market to the detriment of Medicare beneficiaries. A single hospital in an urban county must offer a broad range of services to meet the needs of the Medicare beneficiaries in its large service area while competing with hospitals that offer fewer services yet receive increased reimbursement due to their ability to reclassify. This is exactly the type of situation the geographic reclassification process is designed to address but, due to its unique location, a single hospital in an urban county is unable to reclassify through the general reclassification process.

CMS has consistently recognized the need to provide special treatment for certain hospitals in relation to the wage index and the rules governing geographic reclassification. Most recently, under Section 508(a) of the Medicare Prescription Drug, Improvement and Modernization Act enacted on December 8, 2003, CMS attempted to "alleviate large disparities in wage indices resulting from statutory reclassifications" by providing a one-time appeal process for hospitals whose wage index was at least 10 percent less than the wage index of hospitals located in an adjacent MSA that was reclassified by statute.[8] The Proposed Rule lists TWH's current wage index as 11 percent less than the wage indices of its competitor rural hospitals which have benefited from reclassification. Accordingly, based on CMS's prior determinations of the type of hospitals that should receive special treatment, TWH is justified in receiving special treatment under the wage index.

In addition, in rendering decisions on requests for reclassification, The Medicare Geographical Classification Review Board is required to consider information provided by a hospital applicant with respect to the effects of a hospital's geographic classification on access to inpatient hospital services of Medicare beneficiaries. As explained in the bullet below, unless TWH is able to reclassify, there will be a negative impact on access to inpatient hospital services for Medicare beneficiaries. Accordingly, CMS must level the playing field and provide TWH with fair treatment under the wage index by permitting it to reclassify to the same area where its competitors are located/have been reclassified.

- In evaluating Medicare discharges from FY 2005 HCRIS data, 52% of the total Medicare discharges within a 35 mile radius of TWH have received the benefit of increased Medicare reimbursement due to the wage index reclassification of the respective hospitals treating those discharges. This leaves TWH with having to support 31% of the total Medicare discharges in the 35 mile radius without the benefit of increased reimbursement due to wage index reclassification.

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[8] See 69 Federal Register 7340, at 7342-3.

3. Why should a hospital be allowed to reclassify to a labor market area that is further away than other, closer urban labor market areas?

As explained above, CMS has stated that geographic reclassification should be limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are "located" (physically located or located by reason of being reclassified) in the geographic area to which they seek reclassification. The focus is on *competition*, not location per se. As explained above, the hospitals with which TWH competes (Geisinger and Evangelical) are within 35 miles of TWH as indicated on the map attached at Exhibit 1, but have been reclassified into the Harrisburg MSA. As also explained above, TWH's competitor hospitals are weakening its effectiveness as a health care provider and market participant. Accordingly, the Harrisburg MSA is the appropriate MSA into which TWH should be reclassified.

Permitting a hospital to reclassify to a labor market area that is further away than other closer urban labor market areas is supported by the fact that individual hospitals[9] which are seeking to reclassify to another area are not required to reclassify to the *closest* urban or rural area to the hospital seeking reclassification. As long as they meet the proximity criteria described in Section 412.230(b), they may reclassify into whatever area they choose. Theoretically, a large urban hospital such as TWH that is surrounded by rural hospitals with whom it competes would typically have a higher wage index and a higher average hourly wage than the rural hospitals that surround it. Under these circumstances, one would assume that the rural hospitals surrounding this hospital would seek to reclassify into the closest urban area where its competitor is located. In reality, Geisinger and Evangelical, the rural hospitals surrounding TWH requested and were granted reclassification into the Harrisburg MSA which is located further away than the closer Williamsport MSA, but receives a higher wage index than the Williamsport MSA. These unique circumstances place TWH at a competitive disadvantage which justifies permitting TWH to reclassify to the same MSA where its competitors have been reclassified.

Reclassifying TWH into a closer MSA such as the Scranton-Wilkes-Barre or State College MSA would not be appropriate because: (1) hospitals in these MSAs are not TWH's competitors; (2) historically, these MSAs have had wage indices that have been virtually identical to TWH's[10] and therefore, reclassification into these MSAs would not remedy TWH's disadvantaged status; and (3) while the boundaries of these MSAs may be closer than the boundaries of the Harrisburg MSA, from a market based perspective, TWH competes for staff and patients with, and provides services that exceed or are comparable to the services offered by, Geisinger and Evangelical, both of which have been reclassified into the Harrisburg MSA.

TWH competes for employees with a number of hospitals, but is the only one of these hospitals that does not receive increased reimbursement. TWH has only been able to remain viable and continue to compete with it competitors in the level of services it provides as a result of the efficiencies TWH achieved through its affiliation with SHS in 1994. Now, with no

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[9] With the exception of sole community hospitals and rural referral centers.

[10] Since FY 2001, the wage index for the Scranton-Wiles-Barre MSA and the State College MSA have been negligibly lower/higher (2-4%) than TWH's wage index.

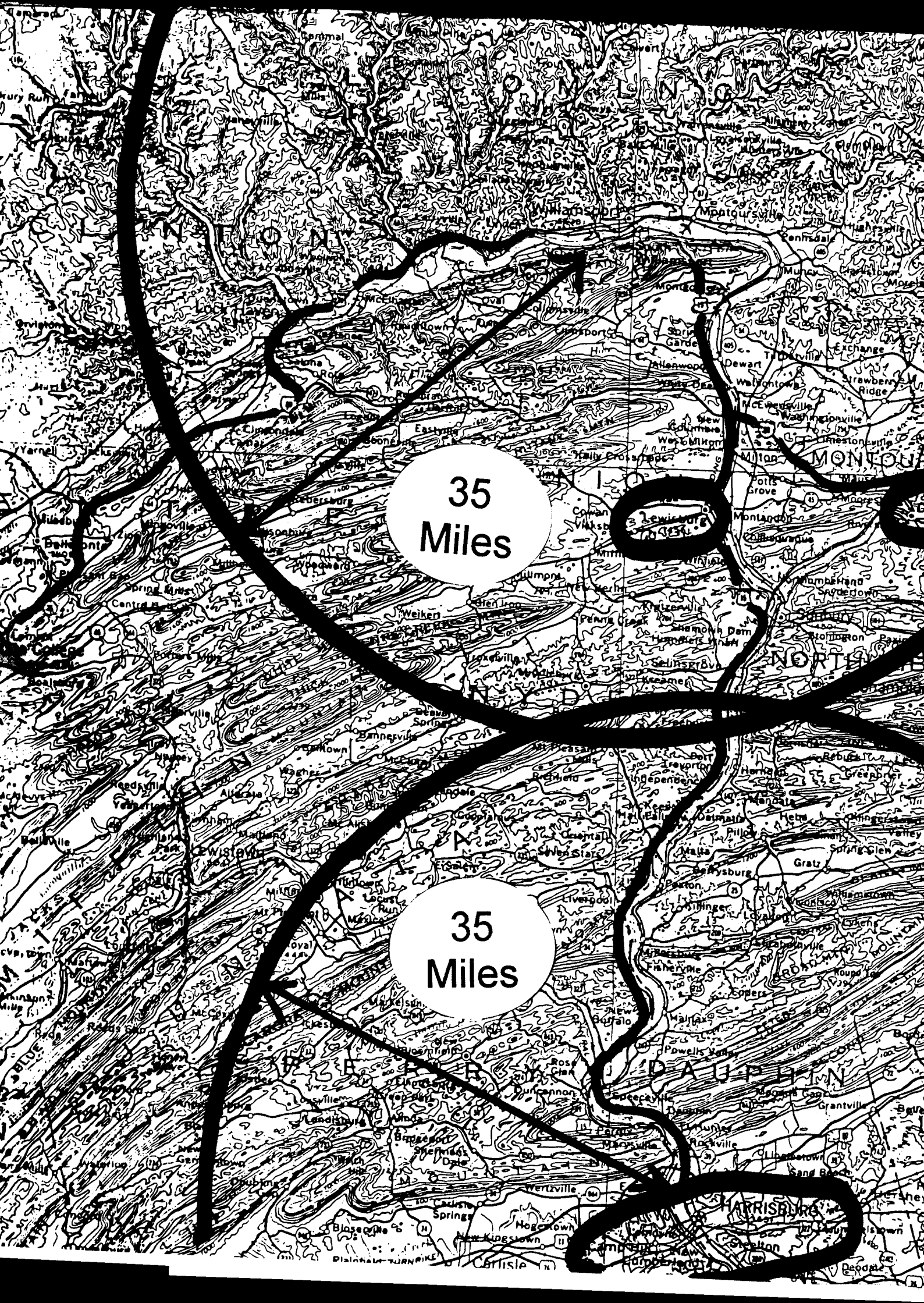
additional costs left to cut and TWH's competitors continuing to receive higher wage indices, TWH is at an unfair competitive disadvantage which will adversely impact the services that TWH is able to provide the community. If TWH is not reclassified into the Harrisburg MSA, TWH will not be able to retain its employees and patient care and access to care will be adversely affected.

We thank you for the opportunity to express our comments to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications" and appreciate your consideration of the issues we raised. As always, we would welcome the opportunity to discuss with you in more detail the special circumstances facing Isolated Hospitals in Single-Hospital MSAs and the advocated changes to the Medicare rules allowing for the reclassification of these hospitals.

Sincerely,

Richard DeWald, Chairman of Board of Directors
The Susquehanna Health System

EXHIBIT 1


35
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11

EXHIBIT 2

SERVICE CONTRAST CHART

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Regional Rural Health Partnership Initiative	Yes	Yes	No	No	No	No
Trauma Center and Emergency Department	Level III Eligible	Yes	No	No	No	No
Infectious Disease Center	Yes	Yes	No	No	No	No
Regional IT Infrastructure and Connectivity Among Hospital Facilities and Health System Physicians	Yes	Yes	No	No	No	No
Comprehensive Electronic Medical Record/Lifetime Clinical Record	Yes	Yes	No	No	No	No
Regional Pharmacy Center ° Supporting 5 Hospitals	Yes	No	No	No	No	No
Comprehensive Community Cancer Center (Accredited)	Yes	Yes	No	No	No	No
Comprehensive Wellness & Health Promotion Center ° LifeCenter	Yes	No	No	No	No	No

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Comprehensive Physical Medicine and Rehabilitation Services (CARF Accredited)	Yes	Yes	No	No	No	No
Comprehensive Stroke Center	Yes	Yes	No	No	No	No
Inpatient Dialysis Center	Yes	Yes	No	No	No	No
Cardiac Surgery	Yes	Yes	No	No	No	Yes
Cardiac Catheterizations	Yes	Yes	No	No	Yes	Yes
Cardiac Angioplasty	Yes	Yes	No	No	No	Yes
Comprehensive Neuroscience Center ° Neurosurgery Services	Yes	Yes	No	No	No	Yes
Family Center for Reproductive Health ° Family Planning Center	Yes (including a Family Planning Center)	Yes (without a Family Planning Center)	No	No	Yes	No
Thoracic Surgery	Yes	Yes	No	No	Yes	Yes
Vascular Surgery	Yes	Yes	Yes	No	Yes	Yes
Palliative Care Program	Yes	Yes	Yes	No	No	No
Comprehensive Pain Management Center	Yes	Yes	No	No	No	No

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Certified Pastoral Education	Yes	Yes	No	No	No	No
PET Scanning/PET CT Fusion	Yes	Yes	Yes	No	No	No
Emergency Ambulance Services	Yes	Yes	Yes	No	No	No
JCAHO Accreditation	Yes	Yes	No	No	Yes	Yes
Comprehensive Referral Laboratory Services	Yes	Yes	No	No	No	No
Comprehensive CME Program	Yes	Yes	No	No	No	Yes
County Forensics Center	Yes	No	No	No	No	No
Diabetes Resource Center	Yes	Yes	No	No	No	Yes
Hyperbaric Chamber Care	Yes	No	No	No	No	No
Helicopter Services	No	Yes	No	No	No	No
NICU	No	Yes	No	No	No	No
Family Practice Residency Training Program	Yes	No	No	No	No	No
Other Physician Residency Training Programs	No	Yes	No	No	No	No
Transplant Services	No	Yes	No	No	No	No

14

EXHIBIT 3

COMPARISON OF NORTH CENTRAL PA HOSPITALS
EMERGENCY ROOM CAPABILITY AND VOLUME

Updated: 3/28/2006

PROVIDER NUMBER	NAME	COUNTY	EMERGENCY CAPABILITY	TOTAL VISITS	E.D. INPATIENT ADMITS	AMBULANCE SERVICE ALS	BLS	AIR	MICU	MCCU
390045	Williamsport Hospital	Lycoming	Comprehensive	50,874	6,282	Yes	Yes	No	Yes	No
390013	Evangelical Hospital	Union	General	28,049	3,849	Yes	Yes	No	No	No
390006	Geisinger Medical Ctr.	Montour	Comprehensive	37,246	6,161	No	No	Yes	No	No
390079	Robert Packer Hospital	Bradford	General	28,182	4,660	No	No	No	No	No
390071	Lock Haven Hospital	Clinton	General	12,773	1,700	Yes	No	No	No	No
390043	Soldiers & Sailors Hosp.	Tioga	General	14,429	1,600	Yes	Yes	No	Yes	No
390246	Charles Cole	Potter	General	9,265	1,348	Yes	No	No	No	No
390072	Berwick Hospital	Columbia	General	13,634	1,968	No	No	No	No	No
390003	Bloomsburg Hospital	Columbia	General	14,086	1,538	No	No	No	No	No
390268	Mt. Nittany Medical Ctr.	Centre	General	40,870	5,229	No	No	No	No	No
Harrisburg Area Hospitals										
390004	Holy Spirit Hospital	Cumberland	General	50,375	9,488	Yes	Yes	No	Yes	No
390256	Hershey Medical Ctr.	Dauphin	Comprehensive	45,044	7,656	Yes	Yes	Yes	No	No
390067	Pinnacle Hospitals	Dauphin	General	78,274	14,157	Yes	No	No	No	No

Source Dept of Health, Annual Hospital Questionnaire - July 1, 2003 through June 30, 2004

Abbreviations:

ALS - Advanced Life Support
BLS - Basic Life Support
AIR - Air Ambulance
MICU - Mobile Intensive Care Unit
MCCU - Mobile Critical Care Unit

EXHIBIT 4

COMPARISON OF NORTH CENTRAL PA HOSPITALS
CASE MIX, WAGE INDEX AND AVERAGE HOURLY WAGE

Updated: 5/15/2006

PROVIDER NUMBER	NAME	COUNTY	CASE MIX INDEX	WAGE INDEX FY2007		AVER. HRLY WAGE FY2005	AVER. HRLY WAGE FY2006	AVER. HRLY WAGE FY2007	3-YEAR AHW FY2007
390045	Williamsport Hospital	Lycoming	1.6290	0.8330		$22.2582	$23.0712	24.0257	23.1327
390013	Evangelical Hospital	Union	1.2264	0.9263	1	23.3180	24.0044	24.9820	24.0935
390006	Geisinger Medical Ctr.	Montour	1.8717	0.9263	1	23.3960	25.1216	26.9964	25.2038
390079	Robert Packer Hospital	Bradford	1.8657	0.8499	1	21.4323	23.3053	22.3152	22.3289
390071	Lock Haven Hospital	Clinton	0.9947	0.8330	1	20.9443	21.8366	25.0434	22.4830
390043	Soldiers & Sailors Hosp.	Tioga	1.2148	0.8330	3	20.9835	22.2549	23.4652	22.2302
390246	Charles Cole	Potter	1.1657	0.8330	3	23.3275	20.1581	25.5357	22.7908
390072	Berwick Hospital	Columbia	1.0662	0.9927	2	22.0155	24.9388	24.8220	23.8819
390003	Bloomsburg Hospital	Columbia	1.1504	0.9927	2	21.3182	21.6478	23.1149	22.0126
390268	Mt. Nittany Medical Center	Centre	1.3621	0.8804		24.2050	25.0021	26.0621	25.1256
390279	Philipsburg Area Hospital	Centre	1.1033			15.3569	17.0012		16.1698
Harrisburg Area Hospitals									
	Holy Spirit Hospital	Cumberland	1.6415	0.9413		23.4063	24.3249	24.8914	24.2683
390256	Hershey Medical Ctr.	Dauphin	1.8697	0.9413		24.2331	26.3619	28.6363	26.4469
390067	Pinnacle Hospitals	Dauphin	1.8178	0.9413		25.4576	26.3287	28.9773	26.8680

	FY2007 AHW		3-Year AHW		Wage Index		GAF	
Williamsport CBSA	24.0257	4	23.2070	4	0.8330	5	0.8824	5
Harrisburg - Carlisle CBSA	27.8666	4	26.2093	4	0.9263	6	0.9489	6
Difference	3.8409		3.0023		0.0933		0.0665	
Difference - %	16.0%		12.9%		11.2%		7.5%	
Rural - Penna. - by CBSA	24.6593	4	23.2635	4	0.8330	7	0.8824	7

Source: Federal Register, 4/25/2006, Proposed 2007 IPPS Rules, Table 2

Notes:

1. Reclassified per Table 9A of Proposed Rules
2. Reclassified per Table 9B of Proposed Rules - Section 508 Reclassification
3. Hospitals are in rural areas and have qualified for Sole Community Hospital status
4. According to Table 3A, 3B FY2007 Average Hourly Wage and 3-Year Average Hourly Wage by CBSA
5. According to Table 4a, the Wage Index and Capital Geographic Adjustment Factor (GAF) by CBSA
6. According to Table 4C, the Wage Index and Capital Geographic Adjustment Factor (GAF) for Hospitals Reclassified
7. According to Table 4B, the Wage Index and Capital Geographic Adjustement Factor (GAF) for Hospitals in Rural Areas by CBSA
8. Mt. Nittany Medical Center in Centre County was formerly Centre Community Hospital

138

Susquehanna Health System
Divine Providence Hospital - Muncy Valley Hospital
The Williamsport Hospital & Medical Center

Richard W. DeWald
Chairman of the Board

Sister Joanne Bednar
Vice Chairman

Steven P. Johnson
President & CEO

June 9, 2006

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates Published in the Federal Register on April 25, 2006

To Whom It May Concern:

Geographic Reclassifications

The following comments are being submitted on behalf of Divine Providence Hospital ("DPH") relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule (the "Proposed Rule") titled "Geographic Reclassifications." DPH is a specialty/psychiatric hospital and part of The Susquehanna Health System ("SHS") in north central Pennsylvania. DPH provides comprehensive behavioral health services, a Liver Disease Center, the Kathryn Candor Lundy Breast Health Center, Susquehanna Cancer Center, Susquehanna Home Care and Hospice, Occupational Health and Sports Medicine, Susquehanna Sleep Disorder Center, Susquehanna Wound Healing Center, Dialysis Services, and the Community Health Center medical and dental clinics. Many of the services provided at DPH are structured to meet the needs of the community and is reflected in the overall patient satisfaction rating at or above the 95% positive standard with 97% of patients indicating that they would return for services or recommend us to friends and acquaintances.

Providing such a broad range of community services requires adequate Medicare reimbursement. As part of SHS the hospital is acutely aware of the financial strain that is placed on the healthcare system due to the wage index reclassification problem at The Williamsport Hospital ("TWH"). DPH strongly supports the advocated changes to the Medicare rules allowing for the reclassification of hospitals located in a single hospital MSAs surrounded by rural counties. The Centers for Medicare & Medicaid Services ("CMS") should immediately adopt these changes to the urban county group reclassification regulations whereby a hospital in a single hospital MSA surrounded by rural counties would be able to reclassify to the closest

urban area that is part of a Combined Statistical Area ("CSA") located in the same State as the hospital.

In what we believe is only two areas of the United States today, there are individual urban hospitals[1] that are the sole hospital in their particular urban area (hospitals in single-hospital MSAs) that have historically found themselves surrounded by rural hospitals with whom they compete that receive higher Medicare payments because they have been reclassified to higher Medicare wage index areas or because CMS considers them rural referral centers, sole community hospitals, critical access hospitals or Medicare dependent hospitals (we will hereinafter refer to these hospitals as "hospitals located in a Single-Hospital MSA surrounded by rural counties").[2] Because these hospitals located in a Single-Hospital MSA surrounded by rural counties operate in urban areas that are not adjacent to any other urban area, they are unable to secure Medicare wage reclassification although they are at a competitive disadvantage because they are competing for labor with hospitals in nearby areas with higher wage indices. They cannot secure Medicare wage reclassification on an individual hospital basis under 42 CFR 412.230 because, according to CMS standards, they are too far from the nearest urban area[3] and, by definition, the ratio of a hospital in a single-hospital MSA's average hourly wage to the average hourly wage of hospitals in the area in which the hospital is located is always 100% and therefore, these hospitals can not meet the 108% threshold for urban hospitals. Similarly, these unique hospitals cannot secure Medicare wage reclassification on a county-wide basis under 42 CFR 412.234 because they are not adjacent to any urban area, for fiscal year 2007, are not part of a consolidated metropolitan statistical area ("CMSA") or combined statistical area ("CSA") that includes the urban area to which they seek redesignation, and for fiscal years 2008 and thereafter, are not part of a CSA that includes the urban area to which they seek redesignation.

Despite the fact that CMS has specifically stated that geographic reclassification is for hospitals that are disadvantaged by their current classification because they compete with hospitals that are located in the geographic area to which they seek reclassification,[4] and that the intent for its FY 2006 proposed changes to the urban group hospital reclassification criteria was "to preserve the reclassification opportunities for urban county groups,"[5] we believe CMS has failed to adequately address the inequities facing a specific subset of urban county groups, namely hospitals located in a Single-Hospital MSA surrounded by rural counties, in relation to the wage index and the rules governing geographic reclassification and is therefore failing to preserve the reclassification opportunities for all urban county groups. The advocated changes described in the Proposed Rule will enable CMS to adequately preserve the reclassification opportunities for urban county groups.

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[1] Unless specified otherwise, the use of the term "hospital" or "hospitals" in this comment letter only refers to hospitals reimbursed under the prospective payment system.

[2] From our research, it appears that only TWH, located in Williamsport, Pennsylvania, Lycoming County (Williamsport, PA MSA) and Community Hospital, located in Grand Junction, Colorado, Mesa County (Grand Junction, CO MSA) meet the definition of hospitals located in a Single-Hospital MSA surrounded by rural counties.

[3] Urban hospitals must be within 15 miles of the urban area into which they seek reclassification for Medicare wage purposes. (Rural hospitals are permitted to be within 35 miles of the area to which they seek reclassification).

[4] June 4, 1991 Final Rule - 56 FR 25469; See also June 2, 1995 Proposed Rule – 60 FR 29202.

[5] May 4, 2005 Federal Register.

The Proposed Rule invited comments on three specific questions concerning the reclassification for hospitals located in a Single-Hospital MSA surrounded by rural counties.

1. What is the justification for reclassifying a hospital that is receiving a wage index reflecting its own wages?

A hospital, such as TWH, that receives a wage index reflecting its own wages is justified in seeking reclassification when its competitors have all been reclassified to and/or are located in an area that receives a wage index reimbursement that is significantly higher than the competitors' actual wages. The geographic reclassification rules have created an anomaly whereby a reclassified hospital may receive wage index reimbursement above its own average hourly wage. This excess reimbursement allows these reclassified hospitals to choose between raising employees salaries or investing in new technology and services. The disadvantage for the hospital receiving a wage index reflecting its own wages that competes with the reclassified hospitals is that it must continually work to keep wages competitive while struggling to purchase new technology and continue to provide the services the Medicare beneficiaries in its community need.

Set forth below are specific examples of why TWH is justified in being reclassified despite receiving its own wage index, including an analysis of TWH's competitors and specific examples of how patient care and access to care will be adversely affected if TWH is not reclassified into the same MSA where its competitors are located and/or have been reclassified.

- TWH's competitor hospitals (in terms of proximity, comparability of services and other factors relevant to geographic reclassification) are Geisinger Medical Center ("Geisinger") and Evangelical Community Hospital ("Evangelical"), both of which have been reclassified into the Harrisburg MSA and thereby receive a higher wage index than TWH, placing TWH at a competitive disadvantage.

  - As shown on the map attached at Exhibit 1, Geisinger and Evangelical are the only PPS hospitals with which TWH competes that are located within 35 miles of TWH. Both Geisinger and Evangelical frequently use billboard, newspaper and radio advertising in Williamsport to recruit patients and staff to their facilities.

  - As shown on the Service Contrast Chart attached at Exhibit 2, the level of services TWH provides is close to that provided by Geisinger and substantially more than that provided by Evangelical. As also shown on the Service Contrast Chart, the level of services TWH provides is similar to that provided by Holy Spirit Hospital which is located in the Harrisburg MSA; and greater than that provided by Lock Haven Hospital, a rural hospital, and Mt. Nittany Hospital which is located in the State College MSA.

  - As shown on the Emergency Room Capability and Volume Chart attached at Exhibit 3, TWH has a significantly larger volume of emergency room visits than all the other hospitals in the region. TWH's volume of emergency room visits is comparable to the volume of emergency room visits of the hospitals located in the Harrisburg MSA, whereas the volume of Geisinger's and Evangelical's

emergency room visits is substantially less than the volume of emergency room visits of the hospitals located in the Harrisburg MSA even though Geisinger and Evangelical have been reclassified into the Harrisburg MSA.

- As shown on the Comparison of North Central PA Hospitals Chart attached at Exhibit 4, TWH's case/mix index is comparable to the case/mix index of the hospitals that are physically located in the Harrisburg MSA and/or have been reclassified into the Harrisburg MSA (e.g., Geisinger) and is notably more acute than the remaining hospitals in the region.

- Historically, TWH's base salary for entry level nurses was comparable to Geisinger's. However, Geisinger is currently able to offer a higher base salary for entry level nurses, a higher signing bonus for nurses[6] and a recent 12% increase in nurse salaries due to the fact that it receives a higher wage index than TWH. TWH's ability to recruit and retain nurses is negatively affected by its inability to offer similar benefits as a result of its receiving a lower wage index. In the long run, this makes it difficult, if not impossible, for hospitals located in a Single-Hospital MSA surrounded by rural counties to recruit and retain the qualified health care professionals they need to serve their communities. This concern is especially significant given the fact that TWH is the only hospital in its urban area and therefore has an even greater obligation to the communities they serve. Without necessary assistance from CMS, the long term financial viability of TWH is questionable.

- For the first time in five years, TWH experienced a significant reduction in its employees' job satisfaction as a result of TWH's inability to provide competitive wages and benefits, as evidenced by a recent internal employee opinion survey.

- TWH has only been able to remain viable and continue to compete with Geisinger and Evangelical in the level of services it provides as a result of the efficiencies TWH achieved through its affiliation (the "Affiliation") with Susquehanna Health System ("SHS") in 1994.[7] These efficiencies were implemented over a 10-year period ending in 2004. Major cost reduction efforts included a 30% reduction in TWH's bed complement from 325 licensed beds to 225, and consolidation/reduction of

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[6] Geisinger is able to offer a signing bonus equal to $4,000 - $5,500 depending on the individual's willingness to work nights and weekends. TWH is only able to offer a $2,000 signing bonus.

[7] Prior to 1994, TWH and its health care affiliates operated as an independent health care system in the Williamsport area known as North Central Pennsylvania Health System ("NCPHS"). At the same time, inpatient and outpatient hospital and other medical services were also provided in the same area by Divine Providence Hospital of the Sisters of Christian Charity ("Divine Providence Hospital"), Muncy Valley Hospital and their affiliates as an independent health care system in the Williamsport area known as Providence Health Foundation ("PHF"). In 1994, the PHF and NCPHS systems, including Divine Providence, Muncy Hospital and TWH, combined their operations having concluded that the effective delivery of high quality, cost effective health care in North Central Pennsylvania required the integration of their operations. The combination was effectuated through the organization of Susquehanna Regional Health Care Alliance (which operates as SHS) and the delegation to SHS of responsibility for overall management and operation of the hospitals and their health care affiliates.

administrative overhead and support services. In addition, of the 282 licensed beds at SHS's other two hospitals (Divine Providence Hospital and Muncy Valley Hospital) 80% or 226 beds were delicensed. As a result, the overall SHS licensed acute bed complement decreased from 607 to 325 or a 54% reduction. Now, with no additional costs left to cut and TWH's competitors continuing to receive higher wage indices, TWH is at a competitive disadvantage which will adversely impact the services that TWH is able to provide the community. While one might suggest that in a market place environment those hospitals with higher labor reimbursements may, in the future, offer additional or expanded services especially when TWH is forced to curtail them, convenient access to these services by less ambulatory seniors will be lost.

- If TWH is not reclassified into the Harrisburg MSA, TWH will not be able to retain its employees and patient care and access to care will be adversely affected as TWH is no longer able to make up the shortfall through any additional cost reduction efforts because it has already achieved a high level of efficiency as a result of the Affiliation. Based on calculations by an auditor engaged by the Pennsylvania Attorney General, SHS realized a net cost savings of $105 million dollars as a result of the Affiliation, yet SHS gave back 117% of its savings to the community in the form of low-cost or no-cost health care programs for the community, reduction in prices and/or limiting actual price increases for existing services, although it was only required by the Pennsylvania Attorney General to return 80% of the net cost savings it achieved as a result of the Affiliation to the community.

- Based on the fact that TWH's top competitors are Geisinger and Evangelical, both of which have been reclassified into the Harrisburg MSA, TWH has clearly demonstrated an economic connection to the Harrisburg MSA.

- TWH is a member of the Susquehanna Valley Rural Health Partnership ("SVRHP") a three-county rural health network of which TWH is the network referral facility. In this capacity, TWH supports a number of hospitals and a federally qualified health care center ("FQHC") including Muncy Valley Hospital, Bucktail Medical Center, Jersey Shore Hospital and Laurel Health which owns and operates the FQHC. If TWH is not reclassified into the Harrisburg MSA, TWH may no longer be able to support these health care organizations by providing IT services, hospital pharmacy services, medical transport services and physician continuing medical education programs.

2. Why should a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals that have received one form or another of special payment status relating to their rural locations, receive special treatment under the wage index?

A hospital should receive special treatment under the wage index when it is a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals ***with whom it competes*** (in terms of services provided, emergency room visits and case/mix) that have received one form or another of special payment status relating to their rural locations. Under these circumstances, the wage index reclassification rules interfere

with a competitive market to the detriment of Medicare beneficiaries. A single hospital in an urban county must offer a broad range of services to meet the needs of the Medicare beneficiaries in its large service area while competing with hospitals that offer fewer services yet receive increased reimbursement due to their ability to reclassify. This is exactly the type of situation the geographic reclassification process is designed to address but, due to its unique location, a single hospital in an urban county is unable to reclassify through the general reclassification process.

CMS has consistently recognized the need to provide special treatment for certain hospitals in relation to the wage index and the rules governing geographic reclassification. Most recently, under Section 508(a) of the Medicare Prescription Drug, Improvement and Modernization Act enacted on December 8, 2003, CMS attempted to "alleviate large disparities in wage indices resulting from statutory reclassifications" by providing a one-time appeal process for hospitals whose wage index was at least 10 percent less than the wage index of hospitals located in an adjacent MSA that was reclassified by statute.[8] The Proposed Rule lists TWH's current wage index as 11 percent less than the wage indices of its competitor rural hospitals which have benefited from reclassification. Accordingly, based on CMS's prior determinations of the type of hospitals that should receive special treatment, TWH is justified in receiving special treatment under the wage index.

In addition, in rendering decisions on requests for reclassification, The Medicare Geographical Classification Review Board is required to consider information provided by a hospital applicant with respect to the effects of a hospital's geographic classification on access to inpatient hospital services of Medicare beneficiaries. As explained in the bullet below, unless TWH is able to reclassify, there will be a negative impact on access to inpatient hospital services for Medicare beneficiaries. Accordingly, CMS must level the playing field and provide TWH with fair treatment under the wage index by permitting it to reclassify to the same area where its competitors are located/have been reclassified.

- In evaluating Medicare discharges from FY 2005 HCRIS data, 52% of the total Medicare discharges within a 35 mile radius of TWH have received the benefit of increased Medicare reimbursement due to the wage index reclassification of the respective hospitals treating those discharges. This leaves TWH with having to support 31% of the total Medicare discharges in the 35 mile radius without the benefit of increased reimbursement due to wage index reclassification.

3. Why should a hospital be allowed to reclassify to a labor market area that is further away than other, closer urban labor market areas?

As explained above, CMS has stated that geographic reclassification should be limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are "located" (physically located or located by reason of being reclassified) in the geographic area to which they seek reclassification. The focus is on *competition*, not location per se. As explained above, the hospitals with which TWH competes (Geisinger and Evangelical) are within 35 miles of TWH as indicated on the map attached at Exhibit 1, but have

[8] See 69 Federal Register 7340, at 7342-3.

been reclassified into the Harrisburg MSA. As also explained above, TWH's competitor hospitals are weakening its effectiveness as a health care provider and market participant. Accordingly, the Harrisburg MSA is the appropriate MSA into which TWH should be reclassified.

Permitting a hospital to reclassify to a labor market area that is further away than other closer urban labor market areas is supported by the fact that individual hospitals[9] which are seeking to reclassify to another area are not required to reclassify to the *closest* urban or rural area to the hospital seeking reclassification. As long as they meet the proximity criteria described in Section 412.230(b), they may reclassify into whatever area they choose. Theoretically, a large urban hospital such as TWH that is surrounded by rural hospitals with whom it competes would typically have a higher wage index and a higher average hourly wage than the rural hospitals that surround it. Under these circumstances, one would assume that the rural hospitals surrounding this hospital would seek to reclassify into the closest urban area where its competitor is located. In reality, Geisinger and Evangelical, the rural hospitals surrounding TWH requested and were granted reclassification into the Harrisburg MSA which is located further away than the closer Williamsport MSA, but receives a higher wage index than the Williamsport MSA. These unique circumstances place TWH at a competitive disadvantage which justifies permitting TWH to reclassify to the same MSA where its competitors have been reclassified.

Reclassifying TWH into a closer MSA such as the Scranton-Wilkes-Barre or State College MSA would not be appropriate because: (1) hospitals in these MSAs are not TWH's competitors; (2) historically, these MSAs have had wage indices that have been virtually identical to TWH's[10] and therefore, reclassification into these MSAs would not remedy TWH's disadvantaged status; and (3) while the boundaries of these MSAs may be closer than the boundaries of the Harrisburg MSA, from a market based perspective, TWH competes for staff and patients with, and provides services that exceed or are comparable to the services offered by, Geisinger and Evangelical, both of which have been reclassified into the Harrisburg MSA.

TWH competes for employees with a number of hospitals, but is the only one of these hospitals that does not receive increased reimbursement. TWH has only been able to remain viable and continue to compete with it competitors in the level of services it provides as a result of the efficiencies TWH achieved through its affiliation with SHS in 1994. Now, with no additional costs left to cut and TWH's competitors continuing to receive higher wage indices, TWH is at an unfair competitive disadvantage which will adversely impact the services that TWH is able to provide the community. If TWH is not reclassified into the Harrisburg MSA, TWH will not be able to retain its employees and patient care and access to care will be adversely affected.

We thank you for the opportunity to express our comments to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications" and appreciate your consideration of the issues we raised. As always, we would welcome the

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[9] With the exception of sole community hospitals and rural referral centers.

[10] Since FY 2001, the wage index for the Scranton-Wiles-Barre MSA and the State College MSA have been negligibly lower/higher (2-4%) than TWH's wage index.

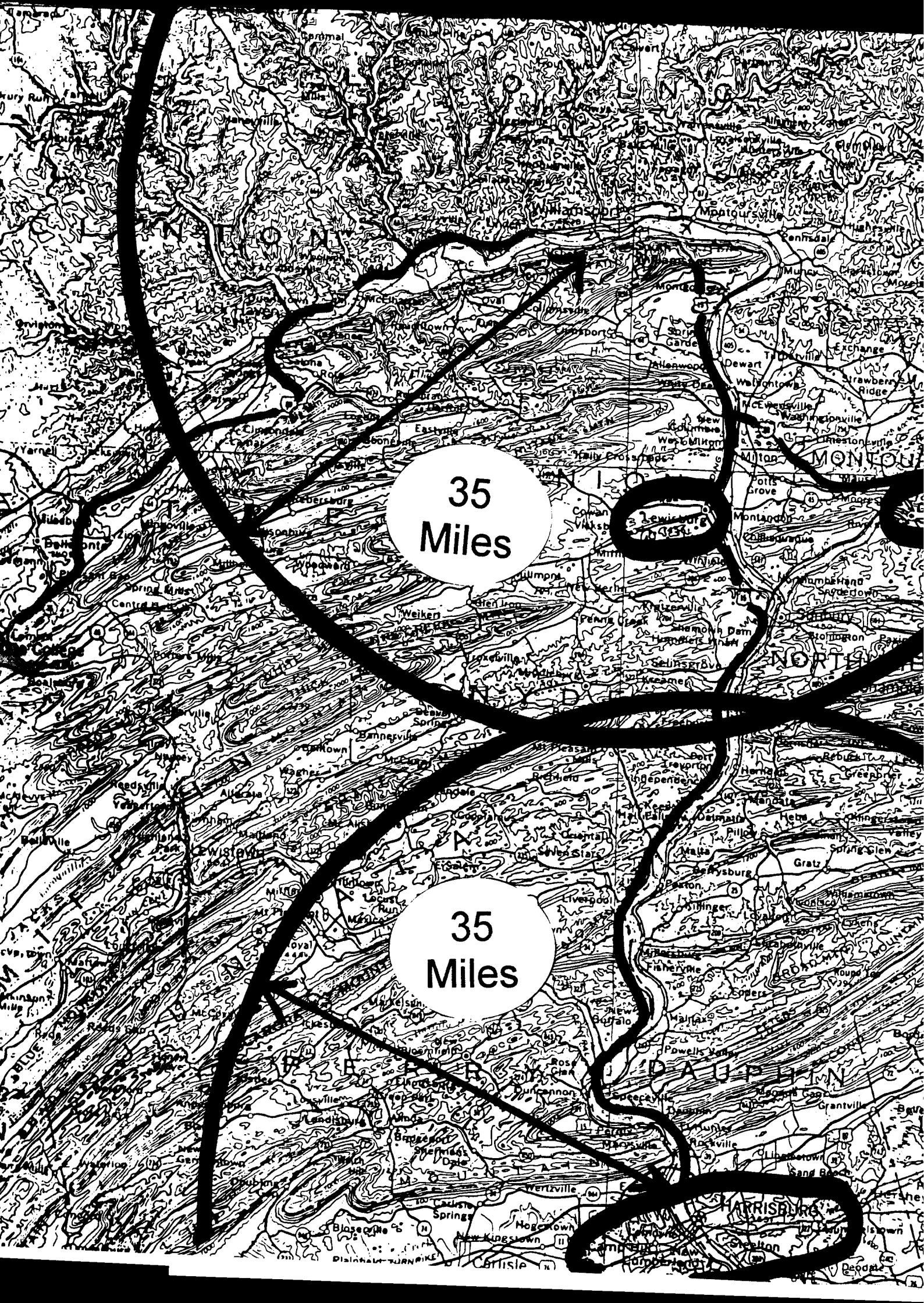
opportunity to discuss with you in more detail the special circumstances facing Isolated Hospitals in Single-Hospital MSAs and the advocated changes to the Medicare rules allowing for the reclassification of these hospitals.

Sincerely,

Sr. Joanne Bednar

Sr. Joanne Bednar, President
Divine Providence Hospital

EXHIBIT 1


35
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11

EXHIBIT 2

SERVICE CONTRAST CHART

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Regional Rural Health Partnership Initiative	Yes	Yes	No	No	No	No
Trauma Center and Emergency Department	Level III Eligible	Yes	No	No	No	No
Infectious Disease Center	Yes	Yes	No	No	No	No
Regional IT Infrastructure and Connectivity Among Hospital Facilities and Health System Physicians	Yes	Yes	No	No	No	No
Comprehensive Electronic Medical Record/Lifetime Clinical Record	Yes	Yes	No	No	No	No
Regional Pharmacy Center ° Supporting 5 Hospitals	Yes	No	No	No	No	No
Comprehensive Community Cancer Center (Accredited)	Yes	Yes	No	No	No	No
Comprehensive Wellness & Health Promotion Center ° LifeCenter	Yes	No	No	No	No	No

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Comprehensive Physical Medicine and Rehabilitation Services (CARF Accredited)	Yes	Yes	No	No	No	No
Comprehensive Stroke Center	Yes	Yes	No	No	No	No
Inpatient Dialysis Center	Yes	Yes	No	No	No	No
Cardiac Surgery	Yes	Yes	No	No	No	Yes
Cardiac Catheterizations	Yes	Yes	No	No	Yes	Yes
Cardiac Angioplasty	Yes	Yes	No	No	No	Yes
Comprehensive Neuroscience Center ° Neurosurgery Services	Yes	Yes	No	No	No	Yes
Family Center for Reproductive Health ° Family Planning Center	Yes (including a Family Planning Center)	Yes (without a Family Planning Center)	No	No	Yes	No
Thoracic Surgery	Yes	Yes	No	No	Yes	Yes
Vascular Surgery	Yes	Yes	Yes	No	Yes	Yes
Palliative Care Program	Yes	Yes	Yes	No	No	No
Comprehensive Pain Management Center	Yes	Yes	No	No	No	No

13

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Certified Pastoral Education	Yes	Yes	No	No	No	No
PET Scanning/PET CT Fusion	Yes	Yes	Yes	No	No	No
Emergency Ambulance Services	Yes	Yes	Yes	No	No	No
JCAHO Accreditation	Yes	Yes	No	No	Yes	Yes
Comprehensive Referral Laboratory Services	Yes	Yes	No	No	No	No
Comprehensive CME Program	Yes	Yes	No	No	No	Yes
County Forensics Center	Yes	No	No	No	No	No
Diabetes Resource Center	Yes	Yes	No	No	No	Yes
Hyperbaric Chamber Care	Yes	No	No	No	No	No
Helicopter Services	No	Yes	No	No	No	No
NICU	No	Yes	No	No	No	No
Family Practice Residency Training Program	Yes	No	No	No	No	No
Other Physician Residency Training Programs	No	Yes	No	No	No	No
Transplant Services	No	Yes	No	No	No	No

14

EXHIBIT 3

COMPARISON OF NORTH CENTRAL PA HOSPITALS
EMERGENCY ROOM CAPABILITY AND VOLUME

Updated: 3/28/2006

PROVIDER NUMBER	NAME	COUNTY	EMERGENCY CAPABILITY	TOTAL VISITS	E.D. INPATIENT ADMITS	AMBULANCE SERVICE				
						ALS	BLS	AIR	MICU	MCCU
390045	Williamsport Hospital	Lycoming	Comprehensive	50,874	6,282	Yes	Yes	No	Yes	No
390013	Evangelical Hospital	Union	General	28,049	3,849	Yes	Yes	No	No	No
390006	Geisinger Medical Ctr.	Montour	Comprehensive	37,246	6,161	No	No	Yes	No	No
390079	Robert Packer Hospital	Bradford	General	28,182	4,660	No	No	No	No	No
390071	Lock Haven Hospital	Clinton	General	12,773	1,700	Yes	No	No	No	No
390043	Soldiers & Sailors Hosp.	Tioga	General	14,429	1,600	Yes	Yes	No	Yes	No
390246	Charles Cole	Potter	General	9,265	1,348	Yes	No	No	No	No
390072	Berwick Hospital	Columbia	General	13,634	1,968	No	No	No	No	No
390003	Bloomsburg Hospital	Columbia	General	14,086	1,538	No	No	No	No	No
390268	Mt. Nittany Medical Ctr.	Centre	General	40,870	5,229	No	No	No	No	No
Harrisburg Area Hospitals										
390004	Holy Spirit Hospital	Cumberland	General	50,375	9,488	Yes	Yes	No	Yes	No
390256	Hershey Medical Ctr.	Dauphin	Comprehensive	45,044	7,656	Yes	Yes	Yes	No	No
390067	Pinnacle Hospitals	Dauphin	General	78,274	14,157	Yes	No	No	No	No

Source Dept of Health, Annual Hospital Questionnaire - July 1, 2003 through June 30, 2004

Abbreviations:

ALS - Advanced Life Support
BLS - Basic Life Support
AIR - Air Ambulance
MICU - Mobile Intensive Care Unit
MCCU - Mobile Critical Care Unit

EXHIBIT 4

COMPARISON OF NORTH CENTRAL PA HOSPITALS
CASE MIX, WAGE INDEX AND AVERAGE HOURLY WAGE

Updated: 5/15/2006

PROVIDER NUMBER	NAME	COUNTY	CASE MIX INDEX	WAGE INDEX FY2007		AVER. HRLY WAGE FY2005	AVER. HRLY WAGE FY2006	AVER. HRLY WAGE FY2007	3-YEAR AHW FY2007
390045	Williamsport Hospital	Lycoming	1.6290	0.8330		$22.2582	$23.0712	24.0257	23.1327
390013	Evangelical Hospital	Union	1.2264	0.9263	1	23.3180	24.0044	24.9820	24.0935
390006	Geisinger Medical Ctr.	Montour	1.8717	0.9263	1	23.3960	25.1216	26.9964	25.2038
390079	Robert Packer Hospital	Bradford	1.8657	0.8499	1	21.4323	23.3053	22.3152	22.3289
390071	Lock Haven Hospital	Clinton	0.9947	0.8330	1	20.9443	21.8366	25.0434	22.4830
390043	Soldiers & Sailors Hosp.	Tioga	1.2148	0.8330	3	20.9835	22.2549	23.4652	22.2302
390246	Charles Cole	Potter	1.1657	0.8330	3	23.3275	20.1581	25.5357	22.7908
390072	Berwick Hospital	Columbia	1.0662	0.9927	2	22.0155	24.9388	24.8220	23.8819
390003	Bloomsburg Hospital	Columbia	1.1504	0.9927	2	21.3182	21.6478	23.1149	22.0126
390268	Mt. Nittany Medical Center	Centre	1.3621	0.8804		24.2050	25.0021	26.0621	25.1256
390279	Philipsburg Area Hospital	Centre	1.1033			15.3569	17.0012		16.1698
Harrisburg Area Hospitals									
	Holy Spirit Hospital	Cumberland	1.6415	0.9413		23.4063	24.3249	24.8914	24.2683
390256	Hershey Medical Ctr.	Dauphin	1.8697	0.9413		24.2331	26.3619	28.6363	26.4469
390087	Pinnacle Hospitals	Dauphin	1.8178	0.9413		25.4576	26.3287	28.9773	26.8680

	FY2007 AHW	3-Year AHW	Wage Index	GAF
Williamsport CBSA	24.0257 4	23.2070 4	0.8330 5	0.8824 5
Harrisburg - Carlisle CBSA	27.8666 4	26.2093 4	0.9263 6	0.9489 6
Difference	3.8409	3.0023	0.0933	0.0665
Difference - %	16.0%	12.9%	11.2%	7.5%
Rural - Penna. - by CBSA	24.6593 4	23.2635 4	0.8330 7	0.8824 7

Source: Federal Register, 4/25/2006, Proposed 2007 IPPS Rules, Table 2

Notes:

1. Reclassified per Table 9A of Proposed Rules
2. Reclassified per Table 9B of Proposed Rules - Section 508 Reclassification
3. Hospitals are in rural areas and have qualified for Sole Community Hospital status
4. According to Table 3A, 3B FY2007 Average Hourly Wage and 3-Year Average Hourly Wage by CBSA
5. According to Table 4a, the Wage Index and Capital Geographic Adjustment Factor (GAF) by CBSA
6. According to Table 4C, the Wage Index and Capital Geographic Adjustment Factor (GAF) for Hospitals Reclassified
7. According to Table 4B, the Wage Index and Capital Geographic Adjustement Factor (GAF) for Hospitals in Rural Areas by CBSA
8. Mt. Nittany Medical Center in Centre County was formerly Centre Community Hospital

Susquehanna Health System
Divine Providence Hospital - Muncy Valley Hospital
The Williamsport Hospital & Medical Center

Richard W. DeWald
Chairman of the Board

Sister Joanne Bednar
Vice Chairman

Steven P. Johnson
President & CEO

139

June 9, 2006

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Published in the Federal Register on April 25, 2006

To Whom It May Concern:

Geographic Reclassifications

The following comments are being submitted on behalf of Muncy Valley Hospital ("MVH") relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule (the "Proposed Rule") titled "Geographic Reclassifications." MVH is a Medicare Critical Access hospital that is part The Susquehanna Health System ("SHS") in north central Pennsylvania. MVH provides selected acute care services, outpatient ancillary and surgical services, emergency department services. long term care services and access to health education and health promotion. As a Critical Access Hospital, we know the difference adequate Medicare reimbursement can make to a hospital. As part of SHS we've experienced the crisis caused by The Williamsport Hospital ("TWH") wage index reclassification problem. MVH strongly supports the advocated changes to the Medicare rules allowing for the reclassification of hospitals located in a single hospital MSAs surrounded by rural counties. The Centers for Medicare & Medicaid Services ("CMS") should immediately adopt these changes to the urban county group reclassification regulations whereby a hospital in a single hospital MSA surrounded by rural counties would be able to reclassify to the closest urban area that is part of a Combined Statistical Area ("CSA") located in the same State as the hospital.

In what we believe is only two areas of the United States today, there are individual urban hospitals[1] that are the sole hospital in their particular urban area (hospitals in single-hospital MSAs) that have historically found themselves surrounded by rural hospitals with whom

[1] Unless specified otherwise, the use of the term "hospital" or "hospitals" in this comment letter only refers to hospitals reimbursed under the prospective payment system.

they compete that receive higher Medicare payments because they have been reclassified to higher Medicare wage index areas or because CMS considers them rural referral centers, sole community hospitals, critical access hospitals or Medicare dependent hospitals (we will hereinafter refer to these hospitals as "hospitals located in a Single-Hospital MSA surrounded by rural counties").[2] Because these hospitals located in a Single-Hospital MSA surrounded by rural counties operate in urban areas that are not adjacent to any other urban area, they are unable to secure Medicare wage reclassification although they are at a competitive disadvantage because they are competing for labor with hospitals in nearby areas with higher wage indices. They cannot secure Medicare wage reclassification on an individual hospital basis under 42 CFR 412.230 because, according to CMS standards, they are too far from the nearest urban area[3] and, by definition, the ratio of a hospital in a single-hospital MSA's average hourly wage to the average hourly wage of hospitals in the area in which the hospital is located is always 100% and therefore, these hospitals can not meet the 108% threshold for urban hospitals. Similarly, these unique hospitals cannot secure Medicare wage reclassification on a county-wide basis under 42 CFR 412.234 because they are not adjacent to any urban area, for fiscal year 2007, are not part of a consolidated metropolitan statistical area ("CMSA") or combined statistical area ("CSA") that includes the urban area to which they seek redesignation, and for fiscal years 2008 and thereafter, are not part of a CSA that includes the urban area to which they seek redesignation.

Despite the fact that CMS has specifically stated that geographic reclassification is for hospitals that are disadvantaged by their current classification because they compete with hospitals that are located in the geographic area to which they seek reclassification,[4] and that the intent for its FY 2006 proposed changes to the urban group hospital reclassification criteria was "to preserve the reclassification opportunities for urban county groups,"[5] we believe CMS has failed to adequately address the inequities facing a specific subset of urban county groups, namely hospitals located in a Single-Hospital MSA surrounded by rural counties, in relation to the wage index and the rules governing geographic reclassification and is therefore failing to preserve the reclassification opportunities for all urban county groups. The advocated changes described in the Proposed Rule will enable CMS to adequately preserve the reclassification opportunities for urban county groups.

The Proposed Rule invited comments on three specific questions concerning the reclassification for hospitals located in a Single-Hospital MSA surrounded by rural counties.

1. What is the justification for reclassifying a hospital that is receiving a wage index reflecting its own wages?

A hospital, such as TWH, that receives a wage index reflecting its own wages is justified in seeking reclassification when its competitors have all been reclassified to and/or are located in

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[2] From our research, it appears that only TWH, located in Williamsport, Pennsylvania, Lycoming County (Williamsport, PA MSA) and Community Hospital, located in Grand Junction, Colorado, Mesa County (Grand Junction, CO MSA) meet the definition of hospitals located in a Single-Hospital MSA surrounded by rural counties.

[3] Urban hospitals must be within 15 miles of the urban area into which they seek reclassification for Medicare wage purposes. (Rural hospitals are permitted to be within 35 miles of the area to which they seek reclassification).

[4] June 4, 1991 Final Rule - 56 FR 25469; See also June 2, 1995 Proposed Rule – 60 FR 29202.

[5] May 4, 2005 Federal Register.

an area that receives a wage index reimbursement that is significantly higher than the competitors' actual wages. The geographic reclassification rules have created an anomaly whereby a reclassified hospital may receive wage index reimbursement above its own average hourly wage. This excess reimbursement allows these reclassified hospitals to choose between raising employees salaries or investing in new technology and services. The disadvantage for the hospital receiving a wage index reflecting its own wages that competes with the reclassified hospitals is that it must continually work to keep wages competitive while struggling to purchase new technology and continue to provide the services the Medicare beneficiaries in its community need.

Set forth below are specific examples of why TWH is justified in being reclassified despite receiving its own wage index, including an analysis of TWH's competitors and specific examples of how patient care and access to care will be adversely affected if TWH is not reclassified into the same MSA where its competitors are located and/or have been reclassified.

- TWH's competitor hospitals (in terms of proximity, comparability of services and other factors relevant to geographic reclassification) are Geisinger Medical Center ("Geisinger") and Evangelical Community Hospital ("Evangelical"), both of which have been reclassified into the Harrisburg MSA and thereby receive a higher wage index than TWH, placing TWH at a competitive disadvantage.

  - As shown on the map attached at Exhibit 1, Geisinger and Evangelical are the only PPS hospitals with which TWH competes that are located within 35 miles of TWH. Both Geisinger and Evangelical frequently use billboard, newspaper and radio advertising in Williamsport to recruit patients and staff to their facilities.

  - As shown on the Service Contrast Chart attached at Exhibit 2, the level of services TWH provides is close to that provided by Geisinger and substantially more than that provided by Evangelical. As also shown on the Service Contrast Chart, the level of services TWH provides is similar to that provided by Holy Spirit Hospital which is located in the Harrisburg MSA; and greater than that provided by Lock Haven Hospital, a rural hospital, and Mt. Nittany Hospital which is located in the State College MSA.

  - As shown on the Emergency Room Capability and Volume Chart attached at Exhibit 3, TWH has a significantly larger volume of emergency room visits than all the other hospitals in the region. TWH's volume of emergency room visits is comparable to the volume of emergency room visits of the hospitals located in the Harrisburg MSA, whereas the volume of Geisinger's and Evangelical's emergency room visits is substantially less than the volume of emergency room visits of the hospitals located in the Harrisburg MSA even though Geisinger and Evangelical have been reclassified into the Harrisburg MSA.

  - As shown on the Comparison of North Central PA Hospitals Chart attached at Exhibit 4, TWH's case/mix index is comparable to the case/mix index of the hospitals that are physically located in the Harrisburg MSA and/or have been

reclassified into the Harrisburg MSA (e.g., Geisinger) and is notably more acute than the remaining hospitals in the region.

- Historically, TWH's base salary for entry level nurses was comparable to Geisinger's. However, Geisinger is currently able to offer a higher base salary for entry level nurses, a higher signing bonus for nurses[6] and a recent 12% increase in nurse salaries due to the fact that it receives a higher wage index than TWH. TWH's ability to recruit and retain nurses is negatively affected by its inability to offer similar benefits as a result of its receiving a lower wage index. In the long run, this makes it difficult, if not impossible, for hospitals located in a Single-Hospital MSA surrounded by rural counties to recruit and retain the qualified health care professionals they need to serve their communities. This concern is especially significant given the fact that TWH is the only hospital in its urban area and therefore has an even greater obligation to the communities they serve. Without necessary assistance from CMS, the long term financial viability of TWH is questionable.

- For the first time in five years, TWH experienced a significant reduction in its employees' job satisfaction as a result of TWH's inability to provide competitive wages and benefits, as evidenced by a recent internal employee opinion survey.

- TWH has only been able to remain viable and continue to compete with Geisinger and Evangelical in the level of services it provides as a result of the efficiencies TWH achieved through its affiliation (the "Affiliation") with Susquehanna Health System ("SHS") in 1994.[7] These efficiencies were implemented over a 10-year period ending in 2004. Major cost reduction efforts included a 30% reduction in TWH's bed complement from 325 licensed beds to 225, and consolidation/reduction of administrative overhead and support services. In addition, of the 282 licensed beds at SHS's other two hospitals (Divine Providence Hospital and Muncy Valley Hospital) 80% or 226 beds were delicensed. As a result, the overall SHS licensed acute bed complement decreased from 607 to 325 or a 54% reduction. Now, with no additional costs left to cut and TWH's competitors continuing to receive higher wage indices, TWH is at a competitive disadvantage which will adversely impact the services that TWH is able to provide the community. While one might suggest that in a market place environment those hospitals with higher labor reimbursements may, in the

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future, offer additional or expanded services especially when TWH is forced to curtail them, convenient access to these services by less ambulatory seniors will be lost.

- If TWH is not reclassified into the Harrisburg MSA, TWH will not be able to retain its employees and patient care and access to care will be adversely affected as TWH is no longer able to make up the shortfall through any additional cost reduction efforts because it has already achieved a high level of efficiency as a result of the Affiliation. Based on calculations by an auditor engaged by the Pennsylvania Attorney General, SHS realized a net cost savings of $105 million dollars as a result of the Affiliation, yet SHS gave back 117% of its savings to the community in the form of low-cost or no-cost health care programs for the community, reduction in prices and/or limiting actual price increases for existing services, although it was only required by the Pennsylvania Attorney General to return 80% of the net cost savings it achieved as a result of the Affiliation to the community.

- Based on the fact that TWH's top competitors are Geisinger and Evangelical, both of which have been reclassified into the Harrisburg MSA, TWH has clearly demonstrated an economic connection to the Harrisburg MSA.

- TWH is a member of the Susquehanna Valley Rural Health Partnership ("SVRHP") a three-county rural health network of which TWH is the network referral facility. In this capacity, TWH supports a number of hospitals and a federally qualified health care center ("FQHC") including Muncy Valley Hospital, Bucktail Medical Center, Jersey Shore Hospital and Laurel Health which owns and operates the FQHC. If TWH is not reclassified into the Harrisburg MSA, TWH may no longer be able to support these health care organizations by providing IT services, hospital pharmacy services, medical transport services and physician continuing medical education programs.

2. Why should a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals that have received one form or another of special payment status relating to their rural locations, receive special treatment under the wage index?

A hospital should receive special treatment under the wage index when it is a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals ***with whom it competes*** (in terms of services provided, emergency room visits and case/mix) that have received one form or another of special payment status relating to their rural locations. Under these circumstances, the wage index reclassification rules interfere with a competitive market to the detriment of Medicare beneficiaries. A single hospital in an urban county must offer a broad range of services to meet the needs of the Medicare beneficiaries in its large service area while competing with hospitals that offer fewer services yet receive increased reimbursement due to their ability to reclassify. This is exactly the type of situation the geographic reclassification process is designed to address but, due to its unique location, a single hospital in an urban county is unable to reclassify through the general reclassification process.

CMS has consistently recognized the need to provide special treatment for certain hospitals in relation to the wage index and the rules governing geographic reclassification. Most recently, under Section 508(a) of the Medicare Prescription Drug, Improvement and Modernization Act enacted on December 8, 2003, CMS attempted to "alleviate large disparities in wage indices resulting from statutory reclassifications" by providing a one-time appeal process for hospitals whose wage index was at least 10 percent less than the wage index of hospitals located in an adjacent MSA that was reclassified by statute.[8] The Proposed Rule lists TWH's current wage index as 11 percent less than the wage indices of its competitor rural hospitals which have benefited from reclassification. Accordingly, based on CMS's prior determinations of the type of hospitals that should receive special treatment, TWH is justified in receiving special treatment under the wage index.

In addition, in rendering decisions on requests for reclassification, The Medicare Geographical Classification Review Board is required to consider information provided by a hospital applicant with respect to the effects of a hospital's geographic classification on access to inpatient hospital services of Medicare beneficiaries. As explained in the bullet below, unless TWH is able to reclassify, there will be a negative impact on access to inpatient hospital services for Medicare beneficiaries. Accordingly, CMS must level the playing field and provide TWH with fair treatment under the wage index by permitting it to reclassify to the same area where its competitors are located/have been reclassified.

- In evaluating Medicare discharges from FY 2005 HCRIS data, 52% of the total Medicare discharges within a 35 mile radius of TWH have received the benefit of increased Medicare reimbursement due to the wage index reclassification of the respective hospitals treating those discharges. This leaves TWH with having to support 31% of the total Medicare discharges in the 35 mile radius without the benefit of increased reimbursement due to wage index reclassification.

3. Why should a hospital be allowed to reclassify to a labor market area that is further away than other, closer urban labor market areas?

As explained above, CMS has stated that geographic reclassification should be limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are "located" (physically located or located by reason of being reclassified) in the geographic area to which they seek reclassification. The focus is on *competition*, not location per se. As explained above, the hospitals with which TWH competes (Geisinger and Evangelical) are within 35 miles of TWH as indicated on the map attached at Exhibit 1, but have been reclassified into the Harrisburg MSA. As also explained above, TWH's competitor hospitals are weakening its effectiveness as a health care provider and market participant. Accordingly, the Harrisburg MSA is the appropriate MSA into which TWH should be reclassified.

Permitting a hospital to reclassify to a labor market area that is further away than other closer urban labor market areas is supported by the fact that individual hospitals[9] which are

[8] See 69 Federal Register 7340, at 7342-3.

[9] With the exception of sole community hospitals and rural referral centers.

seeking to reclassify to another area are not required to reclassify to the *closest* urban or rural area to the hospital seeking reclassification. As long as they meet the proximity criteria described in Section 412.230(b), they may reclassify into whatever area they choose. Theoretically, a large urban hospital such as TWH that is surrounded by rural hospitals with whom it competes would typically have a higher wage index and a higher average hourly wage than the rural hospitals that surround it. Under these circumstances, one would assume that the rural hospitals surrounding this hospital would seek to reclassify into the closest urban area where its competitor is located. In reality, Geisinger and Evangelical, the rural hospitals surrounding TWH requested and were granted reclassification into the Harrisburg MSA which is located further away than the closer Williamsport MSA, but receives a higher wage index than the Williamsport MSA. These unique circumstances place TWH at a competitive disadvantage which justifies permitting TWH to reclassify to the same MSA where its competitors have been reclassified.

Reclassifying TWH into a closer MSA such as the Scranton-Wilkes-Barre or State College MSA would not be appropriate because: (1) hospitals in these MSAs are not TWH's competitors; (2) historically, these MSAs have had wage indices that have been virtually identical to TWH's[10] and therefore, reclassification into these MSAs would not remedy TWH's disadvantaged status; and (3) while the boundaries of these MSAs may be closer than the boundaries of the Harrisburg MSA, from a market based perspective, TWH competes for staff and patients with, and provides services that exceed or are comparable to the services offered by, Geisinger and Evangelical, both of which have been reclassified into the Harrisburg MSA.

TWH competes for employees with a number of hospitals, but is the only one of these hospitals that does not receive increased reimbursement. TWH has only been able to remain viable and continue to compete with it competitors in the level of services it provides as a result of the efficiencies TWH achieved through its affiliation with SHS in 1994. Now, with no additional costs left to cut and TWH's competitors continuing to receive higher wage indices, TWH is at an unfair competitive disadvantage which will adversely impact the services that TWH is able to provide the community. If TWH is not reclassified into the Harrisburg MSA, TWH will not be able to retain its employees and patient care and access to care will be adversely affected.

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[10] Since FY 2001, the wage index for the Scranton-Wiles-Barre MSA and the State College MSA have been negligibly lower/higher (2-4%) than TWH's wage index.

We thank you for the opportunity to express our comments to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications" and appreciate your consideration of the issues we raised. As always, we would welcome the opportunity to discuss with you in more detail the special circumstances facing Isolated Hospitals in Single-Hospital MSAs and the advocated changes to the Medicare rules allowing for the reclassification of these hospitals.

Sincerely,

Robert E. More

Robert E. More, Chairman of the Board of Directors
Munch Valley Hospital

EXHIBIT 1

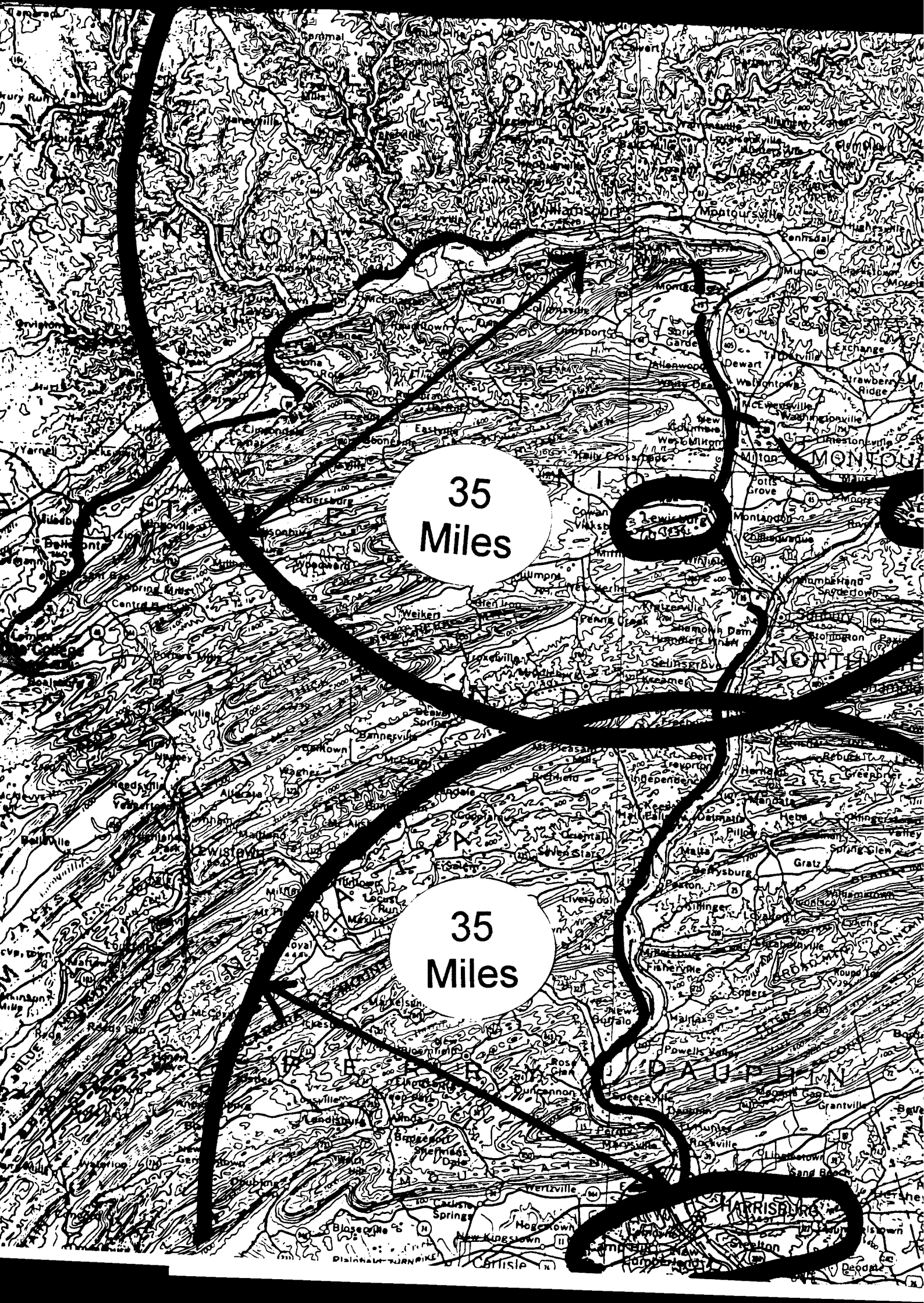
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EXHIBIT 2

SERVICE CONTRAST CHART

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Regional Rural Health Partnership Initiative	Yes	Yes	No	No	No	No
Trauma Center and Emergency Department	Level III Eligible	Yes	No	No	No	No
Infectious Disease Center	Yes	Yes	No	No	No	No
Regional IT Infrastructure and Connectivity Among Hospital Facilities and Health System Physicians	Yes	Yes	No	No	No	No
Comprehensive Electronic Medical Record/Lifetime Clinical Record	Yes	Yes	No	No	No	No
Regional Pharmacy Center ° Supporting 5 Hospitals	Yes	No	No	No	No	No
Comprehensive Community Cancer Center (Accredited)	Yes	Yes	No	No	No	No
Comprehensive Wellness & Health Promotion Center ° LifeCenter	Yes	No	No	No	No	No

12

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Comprehensive Physical Medicine and Rehabilitation Services (CARF Accredited)	Yes	Yes	No	No	No	No
Comprehensive Stroke Center	Yes	Yes	No	No	No	No
Inpatient Dialysis Center	Yes	Yes	No	No	No	No
Cardiac Surgery	Yes	Yes	No	No	No	Yes
Cardiac Catheterizations	Yes	Yes	No	No	Yes	Yes
Cardiac Angioplasty	Yes	Yes	No	No	No	Yes
Comprehensive Neuroscience Center ° Neurosurgery Services	Yes	Yes	No	No	No	Yes
Family Center for Reproductive Health ° Family Planning Center	Yes (including a Family Planning Center)	Yes (without a Family Planning Center)	No	No	Yes	No
Thoracic Surgery	Yes	Yes	No	No	Yes	Yes
Vascular Surgery	Yes	Yes	Yes	No	Yes	Yes
Palliative Care Program	Yes	Yes	Yes	No	No	No
Comprehensive Pain Management Center	Yes	Yes	No	No	No	No

Key High Cost Patient Care Services	The Williamsport Hospital & Medical Center	Geisinger Medical Center Danville	Evangelical Community Hospital	Lock Haven Hospital	Mt. Nittany Hospital State College	Holy Spirit Hospital Camp Hill
Certified Pastoral Education	Yes	Yes	No	No	No	No
PET Scanning/PET CT Fusion	Yes	Yes	Yes	No	No	No
Emergency Ambulance Services	Yes	Yes	Yes	No	No	No
JCAHO Accreditation	Yes	Yes	No	No	Yes	Yes
Comprehensive Referral Laboratory Services	Yes	Yes	No	No	No	No
Comprehensive CME Program	Yes	Yes	No	No	No	Yes
County Forensics Center	Yes	No	No	No	No	No
Diabetes Resource Center	Yes	Yes	No	No	No	Yes
Hyperbaric Chamber Care	Yes	No	No	No	No	No
Helicopter Services	No	Yes	No	No	No	No
NICU	No	Yes	No	No	No	No
Family Practice Residency Training Program	Yes	No	No	No	No	No
Other Physician Residency Training Programs	No	Yes	No	No	No	No
Transplant Services	No	Yes	No	No	No	No

14

EXHIBIT 3

COMPARISON OF NORTH CENTRAL PA HOSPITALS
EMERGENCY ROOM CAPABILITY AND VOLUME

Updated: 3/28/2006

PROVIDER NUMBER	NAME	COUNTY	EMERGENCY CAPABILITY	TOTAL VISITS	E.D. INPATIENT ADMITS	AMBULANCE SERVICE				
						ALS	BLS	AIR	MICU	MCCU
390045	Williamsport Hospital	Lycoming	Comprehensive	50,874	6,282	Yes	Yes	No	Yes	No
390013	Evangelical Hospital	Union	General	28,049	3,849	Yes	Yes	No	No	No
390006	Geisinger Medical Ctr.	Montour	Comprehensive	37,246	6,161	No	No	Yes	No	No
390079	Robert Packer Hospital	Bradford	General	28,182	4,660	No	No	No	No	No
390071	Lock Haven Hospital	Clinton	General	12,773	1,700	Yes	No	No	No	No
390043	Soldiers & Sailors Hosp.	Tioga	General	14,429	1,600	Yes	Yes	No	Yes	No
390246	Charles Cole	Potter	General	9,265	1,348	Yes	No	No	No	No
390072	Berwick Hospital	Columbia	General	13,634	1,968	No	No	No	No	No
390003	Bloomsburg Hospital	Columbia	General	14,086	1,538	No	No	No	No	No
390268	Mt. Nittany Medical Ctr.	Centre	General	40,870	5,229	No	No	No	No	No
Harrisburg Area Hospitals										
390004	Holy Spirit Hospital	Cumberland	General	50,375	9,488	Yes	Yes	No	Yes	No
390256	Hershey Medical Ctr.	Dauphin	Comprehensive	45,044	7,656	Yes	Yes	Yes	No	No
390067	Pinnacle Hospitals	Dauphin	General	78,274	14,157	Yes	No	No	No	No

Source Dept of Health, Annual Hospital Questionnaire - July 1, 2003 through June 30, 2004

Abbreviations:

ALS - Advanced Life Support
BLS - Basic Life Support
AIR - Air Ambulance
MICU - Mobile Intensive Care Unit
MCCU - Mobile Critical Care Unit

EXHIBIT 4

COMPARISON OF NORTH CENTRAL PA HOSPITALS
CASE MIX, WAGE INDEX AND AVERAGE HOURLY WAGE

Updated: 5/15/2006

PROVIDER NUMBER	NAME	COUNTY	CASE MIX INDEX	WAGE INDEX FY2007		AVER. HRLY WAGE FY2005	AVER. HRLY WAGE FY2006	AVER. HRLY WAGE FY2007	3-YEAR AHW FY2007
390045	Williamsport Hospital	Lycoming	1.6290	0.8330		$22.2582	$23.0712	24.0257	23.1327
390013	Evangelical Hospital	Union	1.2264	0.9263	1	23.3180	24.0044	24.9820	24.0935
390006	Geisinger Medical Ctr.	Montour	1.8717	0.9263	1	23.3960	25.1216	26.9964	25.2038
390079	Robert Packer Hospital	Bradford	1.8657	0.8499	1	21.4323	23.3053	22.3152	22.3289
390071	Lock Haven Hospital	Clinton	0.9947	0.8330	1	20.9443	21.8366	25.0434	22.4830
390043	Soldiers & Sailors Hosp.	Tioga	1.2148	0.8330	3	20.9835	22.2549	23.4652	22.2302
390246	Charles Cole	Potter	1.1657	0.8330	3	23.3275	20.1581	25.5357	22.7908
390072	Berwick Hospital	Columbia	1.0662	0.9927	2	22.0155	24.9388	24.8220	23.8819
390003	Bloomsburg Hospital	Columbia	1.1504	0.9927	2	21.3182	21.6478	23.1149	22.0126
390268	Mt. Nittany Medical Center	Centre	1.3621	0.8804		24.2050	25.0021	26.0621	25.1256
390279	Philipsburg Area Hospital	Centre	1.1033			15.3569	17.0012		16.1698
Harrisburg Area Hospitals									
	Holy Spirit Hospital	Cumberland	1.6415	0.9413		23.4063	24.3249	24.8914	24.2683
390256	Hershey Medical Ctr.	Dauphin	1.8697	0.9413		24.2331	26.3619	28.6363	26.4469
390067	Pinnacle Hospitals	Dauphin	1.8178	0.9413		25.4576	26.3287	28.9773	26.8680

	FY2007 AHW		3-Year AHW		Wage Index		GAF	
Williamsport CBSA	24.0257	4	23.2070	4	0.8330	5	0.8824	5
Harrisburg - Carlisle CBSA	27.8666	4	26.2093	4	0.9263	6	0.9489	6
Difference	3.8409		3.0023		0.0933		0.0665	
Difference - %	16.0%		12.9%		11.2%		7.5%	
Rural - Penna. - by CBSA	24.6593	4	23.2635	4	0.8330	7	0.8824	7

Source: Federal Register, 4/25/2006, Proposed 2007 IPPS Rules, Table 2

Notes:

1. Reclassified per Table 9A of Proposed Rules
2. Reclassified per Table 9B of Proposed Rules - Section 508 Reclassification
3. Hospitals are in rural areas and have qualified for Sole Community Hospital status
4. According to Table 3A, 3B FY2007 Average Hourly Wage and 3-Year Average Hourly Wage by CBSA
5. According to Table 4a, the Wage Index and Capital Geographic Adjustment Factor (GAF) by CBSA
6. According to Table 4C, the Wage Index and Capital Geographic Adjustment Factor (GAF) for Hospitals Reclassified
7. According to Table 4B, the Wage Index and Capital Geographic Adjustement Factor (GAF) for Hospitals in Rural Areas by CBSA
8. Mt. Nittany Medical Center in Centre County was formerly Centre Community Hospital

140

WakeMed

Finance
3000 New Bern Avenue
Raleigh, NC 27610
919 350-7106

June 7, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore MD 21244-1850

Re: Medicare Program; Proposed changes to the Hospital Inpatient Prospective Payment Systems and FY 2007 Rates, File Code CMS-1488-P

Dear CMS:

The purpose of this letter is to comment on the Medicare Program' s rule, Proposed Changes to Hospital Inpatient Prospective Payment Systems and FY 2007 Rates. I work for WakeMed Health System in Raleigh North Carolina. I am extremely concerned about the impact the implementation of HSRV weights will have on my organization. Detailed comments are listed below:

HSRV Weights

This provision of the proposed rule negatively reduces reimbursement at our health system by approximately $6.5 million. One of the main reasons CMS is implementing HSRV weights is to reduce the "incentives Medicare payments may provide for the further development of specialty hospitals". WakeMed is a 752 Bed private, non profit Health system. WakeMed consists of two acute care hospitals, one inpatient rehabilitation facility, two skilled nursing facilities, one home health agency, two outpatient facilities and six outpatient rehabilitation facilities. There is no specialty hospital in our system. We provide over $119 million in charity care. We annually treat in excess of 140,000 patients in our emergency rooms. Our emergency room at our Raleigh campus is a level I trauma center. The impact of this provision on our organization is severe. If this provision is implemented it will be extremely difficult for us to continue to provide these services. Thus we are requesting that this provision be eliminated or only be applied to specialty hospitals.

Please contact Jack Dennis at 919 350-7106 or Thomas Meehan at 719 564-0108 if you have any questions.

Sincerely,

Rebecca Andrews

Rebecca Andrews
Vice President, Financial Services

141

Robert H. Bea, CQE
Corporate Vice President
Regulatory and Quality Assurance

June 9, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1488-P: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Calendar Year 2007 Payment Rates

Dear Dr. McClellan:

Siemens Medical Solutions USA, Inc. welcomes the opportunity to provide comments on the proposed 2007 hospital inpatient prospective payment regulation published in the *Federal Register* on April 12, 2006. This notice sets out proposed payment rates for hospital inpatient services offered in calendar year 2006, and it addresses the methodology used to calculate these payment rates.

Siemens Medical Solutions, headquartered in Malvern, Pennsylvania and Erlangen, Germany, is one of the largest suppliers to the healthcare industry in the world. The company is known for bringing together innovative medical technologies, healthcare information systems, management consulting, and support services, to help customers achieve tangible, sustainable, clinical and financial outcomes. Siemens Medical employs approximately 31,000 people worldwide and operates in more than 120 countries.

Siemens appreciates and supports the efforts of CMS to improve the inpatient hospital prospective payment system (IPPS) so that it will more accurately allocate payment for inpatient operating costs. We have a few concerns, however, with the current proposal that we ask CMS to consider as it works towards improvements of IPPS. This year's proposed rule makes sweeping changes to the Medicare inpatient prospective payment system, the largest changes since the payment system was implemented in the early 1980's. These changes focus on two major policy changes: the first recommends using hospital-specific estimated "cost" based weights in calculating DRG payments; the second recommends a more comprehensive method for identifying the patients' severity of illness.

While Siemens believes that CMS should make appropriate changes to the IPPS as needed, the agency should be cognizant of both the need to provide full information on the methodology used to set payment rates to hospitals so that hospitals can weigh the impact of proposed changes, and the need to consider the cumulative effect of changes in the various payment systems it administers on Medicare providers generally. For example, the proposed rule did not make available the patient classification software used to group cases in to new severity-adjusted DRGs, and it departed from what we understand to be standard approaches in using claims data to set DRG payment weights. Hospitals are understandably uncertain in understanding the full impact of the proposed changes in the IPPS, and their approach toward the services they offer in their communities and their technology acquisition decisions will doubtless be impacted considerably.

Further, CMS should recognize that, as it is proposing significant changes in the IPPS, providers are also having to deal with major changes in the Outpatient Prospective Payment System (OPPS) and the Medicare Physician Fee Schedule (MPFS). This compounds the uncertainty associated with making major investments in items like information systems or capital equipment until the payment systems reach some kind of stability. In the meantime, hospitals may be reluctant to make the expenditures need to manage more effectively, and Medicare beneficiaries may not be able to benefit from the most clinically

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effective diagnostic and therapeutic technology. Siemens recommends that any changes of the magnitude of this proposed rule be done in a measured way so that hospitals have sufficient opportunity to evaluate and adapt to these changes and continue to be able to provide appropriate access to care.

HSRV Weights, Cost-Based Weights and Cost Reports: The shift from "charge-based" to "cost-based" reimbursement raises a number of concerns as follows:

- *Data Lag:* A transition from charge-based payment weights to cost-based payment weights would introduce lags in the data used to calculate the rates. The proposed estimated 'cost-based' system relies on Medicare cost reports and Medicare claims. For 2007 rates, CMS would use 2005 Medicare claims; however, cost reports would be used from 2004 and earlier. Additionally, many new technological innovations available in 2007 will not be included in either the claims data or the cost report data used to calculate payment rates.

- *Variation in Hospital Reporting:* The validity of cost report data has diminished over the years. In any given time period, the data may be unreported or unsettled for a significant portion of hospitals. CMS's proposal to use a national approximation for hospital costs appears to ignore individual hospital data that is not available in a particular year. The current system allows approximation if data is not available.

- *Compressing Categories Further Distorts Payment:* In the proposed regulation, CMS bases the estimated costs by sorting estimated costs into 10 groups. This consolidation of categories results in a single category for devices and services. By combining very different products, the estimation process would compress the values for higher cost, low mark-up items and inflate the value of lower cost, high markup items.

- *Estimated Costs:* The 'cost' of a particular item is not an approximation of the actual price the hospital pays for the item, but is a calculation of a charge multiplied by an average markup (a cost to charge ratio) from one of the 10 CMS-designated cost groupings. CMS calculates this 'estimated' cost using a national rate that is specifically designed to ignore what may be legitimate differences in cost structure between hospitals. The calculation penalized hospitals that use new technologies.

- We further understand that the metrics take out the "top" 260 hospitals, subtly biasing the cost structure away from providing the best care to providing average and non-referral center care. This disproportionately impacts our imaging business which is focused on providing the best diagnostic accuracy available, not just the average.

DRGs: Severity of Illness - Data Transparency: CMS needs to provide full and timely access to data and all aspects of the revised methodology to hospitals that must adapt their systems appropriately so as to ensure efficient and cost-effective operation while continuing to provide access to quality care.

Additionally, hospitals, payers and software vendors who provide coding and billing IT solutions, currently have access to the complete DRG classification methodology, which CMS makes publicly available. Complete and timely access to this methodology is critical because the resulting solutions allow hospitals to process and file claims more timely and accurately, avoiding unnecessary denials, rejections and potential false claims. As such, it is important that as CMS changes the DRG system, vendors such as Siemens Health Services retain access to the underlying methodology at an equivalent level of detail. Unfortunately, this does not seem to be the case under the proposed move to an 'All Patient Refined Diagnosis Related Group' (APR-DRG) classification system, which is a proprietary method owned by 3M Health Information Systems. Any information currently extended to hospitals, payers and software vendors regarding this APR-DRG case-mix grouping and severity-adjustment methodology is limited and insufficient to both fully evaluate the proposed rule and implement its proposal.

It is also important that CMS not grant any particular vendor a monopoly, which could potentially raise healthcare costs. CMS' use of this proprietary system would result in a competitive advantage for 3M Health Information Systems over other vendors in the business, including Siemens Health Services, unless CMS were to ensure access to source code, comprehensive system and user documentation, test data and quality support from 3M, at costs commensurate with current costs associated with existing DRG methodology and in advance of implementation of the APR-DRG methodology (i.e, ideally 12 months to ensure effective support to hospitals). CMS' apparent reliance on this proprietary system is in contrast to the open DRG model that CMS has supported since the promulgation of the IPPS in the early 1980's, a model that has been open to public evaluation and discussion. It is essential that any classification system adopted by CMS meet minimal standards of public review, discussion, adaptation and transparency. As such, transparency is critical to advancing affordability in the healthcare system Adoption of this complex system, which is not fully transparent, will increase software acquisition, training and service costs.

Timeframe for Change: The proposed rule calls for implementation to begin as early as October 1, 2006. We do not believe it is realistic to expect hospitals to be prepared for a change to the inpatient hospital payment system of this magnitude in less than five months. Hospitals would not have time to effectively evaluate the impact of the rule, nor effectively plan for and implement the system. Additionally, the timeframe – coupled with the current unavailability of detail regarding the methodology (as discussed above) – would make it impossible for software vendors to support hospitals in this effort through provision of appropriate coding and billing solutions. Additionally, there are a number of other changes that will be implemented concurrently that will impact how hospitals manage and bill Medicare via the IPPS, including the quality initiatives under the Deficit Reduction Act.

We therefore recommend that CMS delay implementation of the proposed rule to allow for adequate time to evaluate the proposal and methodology. Further, we would recommend a transition timeframe for implementation which would allow hospitals to revise their current systems, some in operation for 20 years, and to re-train both their physicians (regarding how patient encounters are documented to better account for severity levels) and their coding staffs, who will need more time under the revised methodology to perform their coding responsibilities. This delay in implementation is critical to ensure that there is no disruption to services provided to Medicare beneficiaries and all hospital patients.

Summary: In summary, Siemens believes this reform in the DRG system, the most significant since the early 1980's, has created uncertainty and speculation: hospitals need time to evaluate the impact to them and time to implement necessary changes to their coding and billing systems. Unfortunately, the current 60-day comment period does not allow adequate time to fully evaluate the impact of these sweeping changes. As such, we recommend that CMS delay implementation of this rule for an appropriate period, minimally one year. Additionally, we request that CMS make available, in advance, sufficient detail about the inputs/data and the new methodology so that hospitals and others can evaluate and comment on whether it should be adopted, assess what they will need to do to operate under the new system, and evaluate access to care.

*****

Thank you for your consideration of our request. Please contact me directly if you would like additional information with respect to our above comments.

Sincerely,

Robert H. Bea
Corporate Vice President Regulatory and Quality Assurance
Chief Compliance Officer
Siemens Medical Solutions USA, Inc.

142

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June 8, 2006

Mark McClellan M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan,

Aurora HealthCare wishes to comment on the April 25th Federal Register entitled, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. Aurora HealthCare owns and operates the following Hospitals in the Eastern Wisconsin area:

Aurora St. Luke's Medical Center	Provider # 52-0138
Aurora Sinai /Medical Center	Provider # 52-0064
Aurora Medical Center – Washington County	Provider # 52-0038
Aurora Medical Center – Oshkosh	Provider # 52-0198
Aurora Medical Center - Manitowoc County	Provider # 52-0034
Aurora BayCare Medical Center	Provider # 52-0193
Aurora Medical Center – Kenosha	Provider # 52-0189
Aurora Medical Center – Sheboygan County	Provider # 52-0035
Aurora Lakeland Medical Center	Provider # 52-0102
Memorial Hospital of Burlington	Provider # 52-0059
West Allis Memorial Hospital	Provider # 52-0139

In particular, Aurora HealthCare would like to comment on the changing of the DRG weight calculation from a charge based to a cost based system, removal of offsite non patient care time for Indirect Medical Education reimbursement, the movement to severity adjusted DRG's, the expansion of number of quality measures to report on, and non payment for infections not present at the time of admission.

DRG Reclassification

Aurora HealthCare takes issue in the re-weighting of the Medicare inpatient DRG's based upon costs rather than billed charges. Our main issues are as follows:

- Not all hospitals have the same cost to charge ratios. In fact, in order to remain competitive, many urban facilities do not mark up expensive surgical supplies such as drug eluding stents and pacemakers, very much at all to keep managed care companies from not authorizing a potentially life saving surgery. These supplies in the CMS calculation are marked up based upon overall department markup, which may not reflect actual supply mark-up.

- Two hundred sixty very large hospitals representing twenty five percent of the total charges were excluded from the cost center cost to charge ratio calculation. However, these hospitals were not exempt from the effects of the DRG weight change, even though the data from their Hospital(s) were not included in the calculation of the DRG weights. Large hospitals offer cutting edge technology services such as Cardiology, and Neurosurgery. Excluding these hospitals from the cost to charge ratio calculation does not give an accurate national cost to charge ratio for modeling purposes.
- Hospitals do not consistently group costs in the same manner on the Medicare cost report. This will lead to cost to charge ratio inaccuracies for the calculation of the DRG payments.
- The cost to charge ratio data used in the calculation is based upon cost report information from 2003. Current technology such as drug-eluding stents, and bi-ventricular pacemakers were in its infancy in 2003, and does not accurately reflect the utilization of these services as it exists today. This leads to inaccuracies in the way these DRG's are proposed to be reimbursed by CMS compared to the actual costs the Hospital incurs for the inpatient stay.
- Cardiology related services will be hit unusually hard in this proposal. As a result of these changes the proposed DRG's for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24%, and pacemakers reduced 12 to 14%. Drug eluding stents cost $3,000 a piece. The average number of stents per patient is 1.65. Cost for drug eluding stents per patient is $4,950. With the average reimbursement for DRG 558 being $7,200, this leaves $2,250 to cover the surgery, all of the other supplies, drugs, and the patient stay of two days. This will not even cover the direct costs much less the overhead it takes to run a hospital. The payment shortfall will have a devastating impact for Cardiology programs across the country, and will potentially cause access problems due to programs not being able to recover the cost of the leading edge technology. This is clearly not the intent of what CMS wanted to do.

With DRG's being a payment system of gains on some DRG's and losses on others, recalculation of the DRG weights based upon costs, will cause a lot more losers than gainers. This could cause hospitals not to invest in expensive life saving treatments due to lack of adequate payment, and therefore inhibit potentially life saving patient care.
Due to the drastic financial effect this has on hospitals, at a minimum this change should delayed for one year, or be phased in over a four year period of time to allow hospitals to adjust to the new payment.

DRG's: Severity of Illness

Aurora HealthCare supports CMS's concept of paying claims more accurately by having severity payment levels within each DRG. However, there needs to be a lot more work done before severity DRG's can be implemented.

- More time is needed before implementation for coding staff training.
- The Severity of illness DRG grouper needs to be released to the public so other information system vendors can perform the necessary programming for medical records and business office software systems. Having 3M maintain control of the grouper software limits access by other software vendors to begin reprogramming of the many of computer systems that needs to have the severity adjusted grouper software and are not compatible with the 3M grouper. This needs to happen well before implementation so hospitals can test their systems, and study the impact on their facilities.

- The new version of the UB-92 needs to be released, so the additional ICD-9 codes beyond nine can be accepted by claims processing system. Without this change hospital providers may not get paid accurately under the severity adjusted system.
- ICD-10 codes need to be implemented in order to obtain an accurate patient diagnosis.
- The effect the severity adjusted payment system has on outliers needs to be studied more closely to make the sure payment is accurate for the resources consumed by the patient.

CMS also needs to take the additional time to implement this so their systems operate smoothly and not create accounts receivable problems for the hospitals.

Hospital Quality Data

Aurora HealthCare supports CMS's effort to expand the number of quality measures hospitals report on in order to receive the full market basket payment increase. However, more time is needed in order for hospitals to implement the expansion. With the final notice not coming out until the beginning of August, and the quarterly data that CMS wants providers to report the expanded data is due on August 15th. That is not enough time for providers to implement the change. Many hospitals use external vendors to compile and submit the data to CMS. Vendors need adequate time to deal with the programming changes necessary to implement the revised quality measures after the regulation is final. Software testing at the hospital needs to be completed to make sure the data is complete and accurate. Aurora HealthCare proposes delaying this provision for at least six months to allow for a smooth implementation.

Value Based Purchasing

Aurora HealthCare is opposed to CMS's recommendation to not pay additional payments for infections acquired while the patient is in the hospital. Hospitals, most of the time, have no control over what the patient complications arise when they are in the hospital. Many visitors who may come to the hospital have drug resistant staph infections, and not even realize it. This can be passed along to the patient quite easily.
Hospital's infection control departments have measures in place to prevent infections as much as they can. However, they cannot possibly control all of the infections all of the time. Hospital's still need to be paid adequately for taking care of the patient, especially the complex hard to treat patient with acquired infections.

FTE Resident Count and Documentation

Aurora HealthCare remains opposed to CMS's interpretation of Public Law 105-33 requiring only patient care time spent be allowed in the FTE count calculation when the Intern or Resident is training outside of the Hospital.
Interns and residents, in order to obtain proper training must spend significant non-patient care time out of the hospital. Time spent at external seminars, reviewing clinic patient charts, researching patient symptoms for related diseases, virtual learning (practice suturing ect.) and documentation coordination with the physician in their clinic, are just of the few of very important functions the Intern or Resident spends doing activities outside of the hospital. These are very essential roles for the education of future

Physicians. Residents are bound to train for a maximum of 80 hours per week, so wherever the resident may have down time, they spend their time on these non - direct patient care functions. Without these functions, the training programs cannot exist.
CMS has made a commitment to fund Graduate Medical Education programs. Without adequate funding by CMS for these programs, many programs will not be able to survive and forced to shut down.

Aurora HealthCare would like to thank CMS for the opportunity to submit our comments on this very important proposed regulation. Should you have any questions, please feel free to call Steve Kowske at 414-647-3429.

Sincerely,

David Eager
Vice President - Finance
Aurora HealthCare

143

WINTHROP
University Hospital

Care without compromise.

John F. Collins, CPA

Vice President-Finance

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June 6, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: 2007 Proposed Rule
CMS-1488-P
HSRV

Dear CMS:

Winthrop University Hospital located in Mineola, New York would like you to consider the following comments with respect the 2007 Proposed Rule specifically related to the HSRV methodology. Winthrop is negatively impacted by the DRG weight component of this proposed change by approximately $8 million.

General Concept

The data used in the formulation of the national RCC is subject to wide variation in cost and charge reporting specifically related to high cost implants that over allocates costs to inpatient routine and creates a new inaccurate bias toward medical DRG's.

A delay of the proposed rule is necessary in order to perform an HSRV base year audit to properly group the cost, gross charges and Medicare charges of a group of supplies that have evolved over time and subsequently never been subject to intermediary scrutiny for proper matching. The appropriate questions to be asked by fiscal intermediaries appear below and should not be difficult to implement by hospitals. The result of this audit would be to generate an accurate RCC which then could be applied to the new modified charge methodology.

Background

The proposed rule begins with a premise that advances in technology and the corresponding charge markups over time generate a bias in the development of charge based weights in favor of providers that offer specialized services. The analysis done by CMS and MedPAC mentions the low cost to charge ratio (RCC) nationally for cardiology and concludes that moving to a cost based relative weight would remove the bias.

Over time, technological advances have been made in medical devices such as stents, pacemakers, defibrillators and orthopedic implants. As the per item cost of these devices was high, many providers moved to consignment purchasing. As group purchasing emerged and lowered the cost, many providers switched back to inventory. At the same time, supply chain operational improvements were being implemented all over the country such as just-in-time inventory and Procedure Based Delivery Systems (PBDS). These operational improvements and consignment purchasing options changed the way supplies flowed through the hospital. Most of these options require the supplier to deliver the implants directly to storage in the operating room, the cardiac catherization laboratory or the Electrophysiology laboratory. As such, the cost of these implants is directly assigned to the ordering department. This is in contrast to pre Inpatient Perspective Payment where most supplies flowed through the central supply department.

Cost Allocation Error

Basic cost report instructions require all supplies to be reclassified on Exhibit A-6 out of their respective departments up to the Central Supply routine cost center and allocated back down through the step down process based on the recommended B-1 statistic "Central Supply Costed Requisitions". The new modes of delivery described above render the traditional cost allocation statistic inaccurate because high cost implants are not issued by the central supply department. Hence, the cost of implants become allocated to inpatient routine as the central supply department currently generates a heavy allocation to the nursing floors because of floor stock requisitions. If an A-6 reclassification is not made, then the cost of implants remain in the directly assigned areas such as the operating room or cardiology. Therefore the RCC for medical surgical supplies is materially understated.

Charges

Most new services added to the Charge Description Master (CDM) for supplies and implants will direct the recap of those charges to the Medical Surgical Supplies Sold ancillary cost center. In situations where implant costs were not reclassified and remain in the directly assigned departments, the charges could either recap in the directly assigned ordering department or the Medical Surgical Supply cost center.

Throughout this time CMS has kept pace and mandated specific revenue codes to be attached to the charge of each device. As such, CMS can easily identify the aggregate charges for these items but also assign these charges to the Medical Surgical Supplies ancillary center for the purpose of determining the RCC. Where the cost and charge remain in the directly assigned area, CMS will classify the Medicare charge for those implants to Medical Surgical Supplies Sold.

Conclusion/New Assumption

The CMS approach to collapse ancillary and routine cost centers into ten RCC groups will not eliminate distortions in the mismatching of costs, charges and Medicare charges described above since the operating room, cardiology, medical surgical supplies and inpatient routine are each one of the ten groups.

It is also likely that the low RCC noticed in certain ancillary areas by MedPac is less indicative of excessive charge markups for devices and more indicative of implant costs ending up in inpatient routine. The over allocation and resulting under pricing of implant DRG's is compounded by the increase in inpatient Room and Board charges that has occurred and been recognized by CMS over the past several years. These charge increases have diluted the impact that an over allocation of implant costs would have on the routine inpatient RCC. The result however under the HSRV methodology is devastating to hospitals providing procedure based services heavily dependent on implants.

Utilizing the raw national RCC data will automatically under these circumstances redistribute revenue away from procedure based services to medical services. This new methodology should be delayed until clear instruction is given to providers to report the cost and charges of implants with the Medical Surgical Supply cost center where the Medicare charges for these services reside. The following issues need to be resolved.

Q-1

Is the cost of implants left in directly assigned ancillary areas on Worksheet A? For example, the costs of pacemakers reside in the operating room while the implant cost for defibrillators are left in the cardiology ancillary center.

Q-2

Are implant gross charges classified on Worksheet C as Medical Surgical? For example, pacemaker gross charges are recapped on your general ledger as operating room and stent gross charges are recapped with the cardiology ancillary center.

Q-3

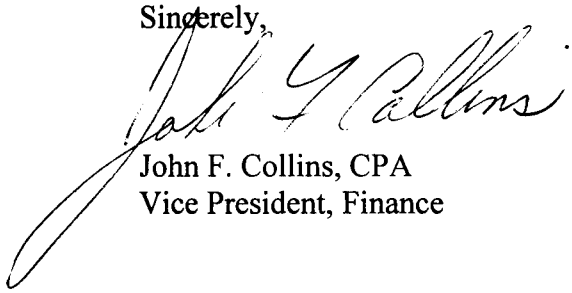
If all supply costs including implants are reclassified up to the routine Central Supply line to be allocated on the B-1 "Costed Requisition" statistic, how was the B-1 statistic modified to recognize that the Central Supply department does not issue implants? If the statistic was not modified, there would be an under allocation of supply costs to the Medical Surgical ancillary line since most pulls from central supply are from the nursing floors.

Q-4

If the B-1 statistic was not modified, were the costs for implants reclassified separately back down to the Medical Surgical ancillary cost center?

If you have any questions, please do not hesitate to contact my office, I have enclosed my business card for your reference.

Sincerely,



John F. Collins, CPA
Vice President, Finance

144

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June 9, 2006

Mr. Tzvi Hefter
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems (IPPS) and Fiscal Year 2007 Rates; Proposed Rule

Dear Mr. Hefter:

We have the following comments on the proposed rule for changes to the hospital IPPS for fiscal year 2007, published in the April 25, 2006, Federal Register.

HOSPITAL QUALITY DATA – PAGE 24095

Public Law (P.L.) 109-171 sets out new requirements for the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. The payment update for FY 2007 and each subsequent year will be reduced by 2.0 percentage points for any hospital that does not submit certain quality data in a form and manner and at a time specified by the Secretary.

Hospitals that wish to appeal this determination have appeal rights through the Provider Reimbursement Review Board (PRRB). However, CMS believes that it may be appropriate to establish a structured reconsideration process to precede the PRRB appeal. We concur with CMS that it is appropriate to establish a structured reconsideration process to precede the PRRB appeal in situations where hospitals have failed to meet the RHQDAPU program requirements for hospital data submission. Currently, there is an informal process in which hospitals submit letters detailing their reasons for requesting that CMS reconsider its decision. Since CMS has indicated that it is satisfied with this informal process, we recommend that this be the basis for the structured process.

We recommend that if CMS formalizes a pre-appeal reconsideration process, it should clearly inform hospitals of the procedures to follow and of their appeal rights. The notification of appeal rights should specify the determination date from which the provider can appeal, whether it is the date of the original CMS notification or the date of CMS' response to the reconsideration request. In addition, CMS should also indicate if the pre-appeal reconsideration process is mandatory or optional for the hospitals.

As an alternative, CMS should consider expanding the Intermediary Appeals process for a reconsideration process. The Intermediary Appeals process would be independent from CMS, already has an established process, and can be completed timely.

SOLE COMMUNITY HOSPITAL(SCH)/MEDICARE-DEPENDENT HOSPITAL (MDH) VOLUME DECREASE ADJUSTMENT - PAGE 24101

An SCH or MDH that experiences a decrease of more than 5 percent in its total number of inpatient discharges from one cost reporting period to the next can get a payment adjustment. CMS is proposing an alternative method for determining an SCH's or MDH's target number of core staff using data from the Medicare cost report and the occupational mix survey instead of currently used, but outdated HAS/Monitrend information.

CMS indicated that the proposed methodology would be used beginning with requests for adjustments for FY 2008 cost reports. It is not clear to which cost reports CMS is referring. We recommend that CMS specifically identify the cost reports to which this change will be applicable, i.e., cost reports beginning on or after Oct. 1, 2007, or cost reporting periods ending after Oct. 1, 2007.

If a hospital has applied for, and been rejected for, a volume decrease adjustment based on the methodology using the HAS/Monitrend data, can it apply for a reassessment under this new methodology if it would yield a more favorable result? We recommend that CMS be very specific in identifying the application of the proposed methodology.

DISPROPORTIONATE SHARE HOSPITALS (DSH) ADJUSTMENT - PAGE 24107

Section 951 of the Medicare Modernization Act (MMA) allows hospitals to request and receive SSI data from CMS in relation to their DSH adjustment. Now that the provider can request the SSI data, what is the timetable for them being able to get the information? Is there a certain date by which they need to make the request? In addition, is there a certain timeframe that has to pass before the provider can request the data? For example, for a FYE June 30, 2005, cost report, when would the data be available from CMS, so that it could fill the provider's request for data for this year-end?

In addition, we note that there is no way for the intermediaries to verify and test the SSI data, even if the provider does obtain it. What should the intermediary do if the provider requests and obtains its SSI data and requests the intermediary to use it in determining the DSH adjustment?

DIRECT GRADUATE MEDICAL EDUCATION (GME) PAYMENTS - PAGE 24111

Determination of Per Resident Amounts for New Teaching Hospitals - Page 24113

CMS proposes that a Per Resident Amount (PRA) determination will be made even where residents are not on duty in the first month of a cost reporting period but where residents began training in the prior cost reporting period. Effective for cost reporting periods beginning on or after Oct. 1, 2006, if a new teaching hospital begins training residents in a cost reporting period beginning on or after Oct. 1, 2006, and no residents are on duty during the first month of that period, the PRA will be established using: 1) the cost and resident data from the cost reporting period immediately following the one for which GME training at the hospital was first reported (the base period); or 2) the updated weighted mean value of the PRAs of all hospitals located in the same geographic area. As with existing policy, the proposed base year need not be a full cost reporting period.

CMS should state that the PRA will be based on "the lesser of" the cost and resident data from the cost report, or the updated weighted mean value of the PRAs of all hospitals located in the same geographic area.

RESIDENT TIME SPENT IN NON-PATIENT CARE ACTIVITIES AS PART OF APPROVED RESIDENCY PROGRAMS - PAGE 24114

CMS notes on page 24115 that "hospital complex" has been defined in the Sept. 29, 1989, Federal Register, as the hospital, and the hospital-based providers and subproviders.

The Sept. 29, 1989, Federal Register indicates that hospital-based providers are facilities such as skilled nursing facilities (SNFs) or home health agencies (HHAs).

On Aug. 1, 2002, CMS published revised regulations (42 CFR 413.65) regarding the requirements for determining if a facility or organization qualified for provider-based status. It is our understanding that if a provider qualifies as provider-based under this regulation, the facility will be considered part of the hospital complex. If that is the case, we recommend that it be clarified in the final rule.

We believe this clarification is necessary because, based on the 1989 Federal Register, only facilities such as SNFs and HHAs (facilities that bill Medicare and have direct patient care activities) can qualify as provider-based. In fact, for example, a separate building where only research is conducted may qualify for provider-based status and should be included as part of the hospital complex.

NURSING AND ALLIED HEALTH EDUCATION ACTIVITIES - PAGE 24116

The regulations state that effective Oct. 1, 2003, programs in which employees participate that do not lead to the ability to practice and begin employment in a nursing or allied health specialty are treated as normal operation costs. CMS is clarifying that this provision applies to both employees and trainees. We recommend that CMS make a regulation revision to reflect that trainees are included in the normal operation costs to avoid confusion.

Thank you for the opportunity to comment on the proposed rule. Please call me at 312.297.5876 if you have any questions on our comments.

Sincerely,

Michael W. Harty
Director
Strategic Government Initiatives

145

KYPHON

June 6, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-8010

RE: CMS-1488-P-Medicare Program; Proposed Changes to the HIPPS and FY 2007 Rates

Dear Dr. McClellan:

Kyphon welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Medicare hospital inpatient prospective payment system ("HIPPS") proposed rule for fiscal year 2007 (the "Proposed Rule"). Kyphon is the leading manufacturer of innovative medical devices for performing balloon kyphoplasty, which is a minimally invasive treatment for spinal fractures caused by osteoporosis or cancer. By achieving fracture stabilization and correction of spinal deformity, patients experience significant reduction in pain and improvement in mobility, thus reducing both the number of days in bed and the use of analgesics and other medicines for managing pain and increasing their overall quality of life. Appropriate Medicare reimbursement for balloon kyphoplasty is important to ensure that patients have access to this procedure.

For this reason, Kyphon wishes to commend CMS for embarking on an overhaul of the HIPPS/DRG system and striving to establish more appropriate Medicare payment for hospital inpatient services. In this letter Kyphon would like to highlight a number of areas of particular importance to our hospital customers. These are outlined in our Executive Summary and discussed below.

I. EXECUTIVE SUMMARY

CMS has proposed two major reforms related to HIPPS and diagnosis related groups ("DRGs"):

(1) Basing the DRG relative weights on estimated hospital costs rather than charges (referred to as HSRVcc weights), and
(2) Adjusting the DRG system to account for patient severity.

We support CMS's decision to implement more appropriate HIPPS payment and our recommendations and comments are discussed below.

Cost-Based Weights

- **Implement cost-base weight changes together with severity adjustments in FY 2008.** We agree with MedPAC and CMS that cost-based weights should be implemented together with the DRG severity adjustments. However, in order to give hospitals adequate time to make such adjustments, we recommend that any modified cost-based weighting system should be implemented in FY 2008 (or later) together with appropriate severity adjustments.

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- **Preserve and maintain beneficiary access to appropriate medical care**. To ensure appropriate payment to hospitals, CMS may wish to consider alternatives to the HRVcc's methodology. One potential alternative is the development of cost-based weights calculated using individual, hospital-specific aggregate cost-to-charge ratios, rather than national average cost centers. Another alternative is the cost-based weighting system that CMS uses for the hospital outpatient prospective payment system. If CMS does adopt HSRVcc weights, it should work to ensure the accuracy of the underlying data.

Severity of Illness Adjustments

- **Support patient severity of illness adjustments**. Kyphon supports DRG reforms designed to account for patient severity of illness. However, if CMS adopts severity-adjusted DRGs, it should appropriately recognize technologies that represent increased complexity, but not necessarily greater severity of illness.

- **Consider maintaining current DRG structure with severity adjustments**. CMS should consider splitting the current DRGs to reflect the severity of cases within each of the DRGs. Keeping the current, albeit refined DRG system would enable CMS to build upon the improvements that have been made in the DRG structure in recent years to account for new technologies.

Kyphoplasty

- For 2007, CMS is proposing to continue to pay for kyphoplasty procedures under DRGs 233, 234, 442, 443 and 486.

- CMS proposes to conduct additional analysis of the spine/musculoskeletal DRGs and develop a severity-adjusted DRG system which takes into account the innovations occurring in spinal surgery over the last several years. Although we support CMS's overall goals and support severity-adjusted DRGs, we do want to recommend that CMS implement a mechanism to adequately capture hospitals' costs associated with complex spinal procedures that use advanced medical technology, and urge CMS to adopt such mechanisms. Going forward, we support CMS's continued review and refinement of the DRGs involving spinal procedures to facilitate appropriate hospital payment.

- If for any reason there is a delay in implementation beyond next year or so, we would ask CMS to review and consider re-assignment of kyphoplasty procedures to a more clinically appropriate DRG which better reflects the resources involved.

II. COMMENTS ON PROPOSED RULE

A. Proposed Revisions to the DRG System

We share CMS's goal of providing appropriate and accurate payment for Medicare inpatient procedures and applaud CMS's decision to update the HIPPS/DRG payment system. However

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as discussed below, given the magnitude of the proposed changes and the potentially significant impact on hospitals and patients, we urge CMS to defer adopting sweeping DRG reforms in 2007 in order to implement the cost weighting changes together with the severity adjustments.

1. HSRV Weights

CMS proposes to change the basis for the weights assigned to DRGs from hospital charges to estimated hospital costs, effective October 1, 2006. CMS refers to this weighting system as the hospital-specific relative value cost center, or HSRVcc methodology.

CMS expects that adoption of the HSRVcc weights would decrease payment for some surgical DRGs and increase payment for other surgical and medical DRGs. In light of the proposed impact on patient access to advanced medical care, we believe that CMS should consider alternatives to the HSRVcc weights that offer more appropriate reimbursement to hospitals for advanced surgical care.

One potential alternative for CMS to consider is the development of cost-based weights calculated using individual, hospital-specific aggregate cost-to-charge ratios, rather than national average cost centers. Another alternative is for CMS to adopt cost-based weights similar to the system used under the hospital outpatient system.

With regard to the timeline for implementation, we agree with MedPAC that cost-based weights should be implemented together with the patient severity of illness adjustments. Thus, we recommend that CMS continue to develop its DRG reform methodology during FY 2007 in order to assure that the methodology results in payments that are as accurate as possible and that patient access to medical care is preserved. Then, beginning in 2008, CMS could move forward with implementation of a cost-based weighting system together with DRG severity adjustments.

2. DRGs: Severity of Illness Adjustments

The second DRG reform in the Proposed Rule would adjust relative weights to reflect severity of illness among patients. Specifically, CMS proposes to replace the 526 current DRGs with approximately 861 DRGs adjusted for patient severity. These 861 DRGs are based on 3M's All Patient Refined Diagnosis Related Group System ("APR DRG").

We support CMS's decision to implement adjustments to the DRG system to better account for the severity of illness associated with individual patient cases. We agree that patient severity of illness adjustment could result in payments that are more accurate to hospitals. We do, however, have some concerns with respect to the specific severity of illness adjusted DRG system proposed by CMS. Most importantly, as CMS pointed out, the consolidated severity-adjusted DRG methodology does not accommodate accurate assignment of payment for complex cases that involve the use of newer and most generally expensive medical technology and "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system."

One potential mechanism would be to overlay severity adjustments on the current DRG structure, i.e., split the current DRGs as appropriate to reflect the severity of cases within the DRG. This would have the advantage of building upon the improvements that have been made in the DRG structure in recent years to account for new technologies. Another alternative would

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be to designate certain DRGs as device-dependent and ensure that the costs of such devices are appropriately reflected in the claim file data. We are confident that delaying implementation will provide CMS additional time to work with stakeholders over the next year to study modifications to the proposed severity-adjusted DRG system and alternative systems that would account for the resources associated with complex and costly medical technology procedures.

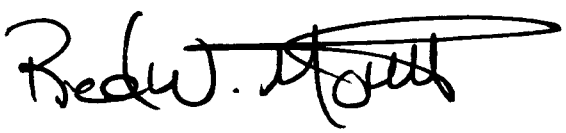
B. DRGs: Kyphoplasty

CMS specifically recognized kyphoplasty as one of a number of innovations in spine surgery in the past several years (see 71 Fed. Reg. at 24036). That said, CMS proposes to defer further analysis of the spine DRGs and address refinements to the system through severity-adjustments in 2008.

Adequate payment for kyphoplasty is essential to assure that patients have access to this procedure. Therefore, we do have concerns that delay in refining the DRGs could possibly result in hospital reluctance to provide this therapy if there is a substantial negative financial impact on the hospital budget. For this reason, we defer to and support our hospitals in their comment letters on this payment issue and support CMS's overall goal of establishing more accurate payment.

We appreciate your attention to our comments and would be pleased to provide additional information or discuss any of these issues in greater detail.

Sincerely,



Richard W. Mott
President and Chief Executive Officer
Kyphon Inc.

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146

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June 5, 2006

Mark McClellan, MD, PhD, Administrator
Center for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8011
Baltimore, Maryland 21244-1850
Attn: CMS-1488-P

Dear Dr.McClellan:

Thank you for the opportunity to comment on the Center for Medicare and Medicaid Services proposed rule for the FY 2007 Inpatient PPS update, published in the *Federal Register* of April 25, 2006. I am the Vice President for Financial Policy for the West Virginia Hospital Association, which represents 73 hospitals and health systems in the state.

I am concerned regarding a number of provisions in the proposed rule, and particularly wish to comment on CMS' proposed changes to the DRG weighting system to be used in the Inpatient PPS system.

The West Virginia Hospital Association believes that one of the goals of the Inpatient PPS should be to provide for an opportunity for return across all DRG's, so as to provide equal incentives to treat all types of patients and conditions. While we support the general approach that CMS is taking in its proposed rule, we are concerned that there may be both technical errors with the proposed cost-based DRG weights, as more fully described by the American Hospital Association in its comment letter to you. In addition, it is unclear to us as to why the proposed severity-based system would be delayed for one year, particularly when it will offset many of the impacts (both negative and positive) of the move to the cost-based weights. As a result, the WVHA would recommend to CMS the following:

- A one-year delay in the implementation of any proposed move to cost-based weights, to assure the accuracy of the cost-based weight methodology;
- Should a severity-based system be adopted, it should be adopted at the same time as a move to the cost-based weights; and,
- Given the significant financial impact and redistributive effect of any proposed changes to the weighting methodology, such changes should be implemented over at least a three-year time period, similar to previous changes to other aspect of the IPPS and other PPS system changes that CMS has implemented over the past several years.

In addition to the concerns addressed above, WVHA believes that the outlier threshold needs to be adjusted to assure that the full 5.1% of IPPS payments are devoted to outliers, as required. The Association also wishes to indicate its support for the move to collection

of additional quality data from hospitals, provided that sufficient advance notice is provided to allow for hospitals to work with their information systems vendors and contracts to allow for this additional data collection.

I appreciate the opportunity you have given the Association to respond to your proposed rule, and look forward to your response to the concerns we have raised above in your publication of the final IPPS rule.

Michael B. Robbins
Vice President/Financial Policy

Saint Thomas Hospital
A Member of Saint Thomas Health Services

Date May 22, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Saint Thomas Hospital is a 541-bed, acute care, faith-based, not-for-profit facility located in Nashville, Tennessee. Since its inception in 1898, Saint Thomas has evolved into a tertiary referral center for many especially complex procedures including cardiac services. As a nationally recognized center for superior cardiac care, we implant devices, provide access to new technologies and treatments, including heart transplants, and receive clinically complex referrals from the surrounding region for hundreds of miles. Our hospital provides care for approximately 12,500 traditional Medicare inpatient admissions per year and an additional 1,200 Medicare Advantage cases annually. The services provided at Saint Thomas are not cardiac alone and range throughout a variety of areas in adult medicine and surgery, including orthopedics, neurosciences, emergency medicine, pulmonary medicine, oncology and hematology to name only a few. Unfortunately, as a result of developing our particular expertise in the area of cardiac services, our hospital stands to lose $13.6 million in Medicare reimbursement, if the proposed prospective payment rule is adopted as drafted. A loss of $13.6 million dollars will significantly hurt our hospital's ability to support ongoing significant investments in technology and clinical expertise and will put at risk the excellent programs our organization has developed. Thus, in response to your request for comments on the Proposed IPPS for fiscal 2007, I am writing to express my utmost concern regarding the published recommendations to change the way Medicare pays for inpatient services.

In particular, I have the following concerns about the proposed changes:

1. **First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver complex cardiology and neuroscience services.**

   The intent appears to be to target 'Specialty Hospitals', yet all hospitals with significant cardiology, orthopedic joint replacement and/or neurosurgery services will suffer major reductions in payment for such services regardless of whether they fit this definition. Supposed offsetting increases to selected DRGs intended to neutralize the overall impact to hospitals do not appear proportionate to the decreases, when one considers the impact of removing low Medicare volume DRGs such as pediatrics and

obstetrics; rare and specialized DRGs such as transplants, behavioral health and burn categories and eliminates cases rarely done in an inpatient setting from the calculation.

The proposed rule instead appears to target high volume, high dollar implant cases particularly in the areas of neurosurgery and cardiology for reductions of 25% -36%. This compares to only modest increases for the most prevalent medicine DRGs in these same service categories such as CHF (DRG 127- 2.9% increase in relative weight) or Stroke (DRG 14- 0.2% increase in relative weight). The intent may have been to eliminate reimbursement incentives for specialty hospitals to steer the most profitable cases to themselves, but the result appears to be punitive to all hospitals serving the most prevalent diagnoses within the Medicare population.

2. **Second, it adopts "cost-based" DRG weighting in place of the current charge based system without accounting for tiered mark-ups on high dollar supplies and inconsistent mapping of supplies to cost report lines among providers.**

It is common industry practice to have higher cost line items charged at a lower mark-up than relatively lower cost items. The methodology for instituting the proposed 'cost basis' however, does not account for the fact that the supply mark-up cost to charge ratio that is calculated from the data is the result of an average of all supplies, not just the specific supplies used in the services that are being isolated for payment recalculation. The result materially underestimates the true cost of any DRG with a disproportionate amount of total charges represented by supply items that are marked up at a rate less than the average mark-up (thus having a higher than average cost to charge ratio). This misapplication of the supply ratio inappropriately reduces payments for cardiology procedures featuring high cost device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. (DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.)

If CMS is determined to pursue this methodology it is a reasonable expectation on the providers' part that an indication of the change in method be given in sufficient time prior to execution for providers to take steps to improve the accuracy of the source information being used. Mandating a common mark-up on all supplies to ensure the validity of the ratio derived or setting aside a specific cost report line for such targeted supplies are options available for gathering this data on a go-forward basis.

It is not intuitive that any hospital would mark-up a $25,000 implant at the same rate it would a $250 implant, in this charge conscious industry. If it is CMS's desire that providers <u>should</u> <u>do so</u> in order to ascertain a more accurate ratio calculation, then such expectations should be made clear and the public prepared for the consequences

in the form of exponentially higher charge totals for procedures that entail use of high cost implants and devices.

Alternatively, if there are high dollar implants that CMS wishes to segregate without mandating pricing, then unique revenue codes should be set aside for just such line items with specific cost report mapping required consistently among all providers. The proposed rule's methodology instead takes revenue codes that represent a wide variety of supplies, supply mark-ups and services and then makes assumptions about the mapping of their cost and charges without accounting for the disparity among providers' cost reports. Subscripted cost report lines specific to cardiology services that were omitted as part of CMS's initial analysis are evidence of the pitfalls of using this data source in the absence of clear guidelines provided **in advance** for how and where data is expected to be recorded.

3. **With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases.**

The proposed APR-DRG system only acknowledges complications of the case and co-morbidities of the patient. Tools for abstracting complexity and the presence of new technologies however are severely hampered by the current ICD-9 codes available. Emerging and expensive technologies that are intended to extend the mobility and health of a patient who does not fall into a high-risk APR-DRG stratification would not be accounted for in the proposed reimbursement methodology, thus limiting access to these technologies to Medicare beneficiaries in the long run.

The payment methodology changes that CMS has proposed would have a severe financial impact on our hospital – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital's actual cost to deliver these services. The reduction in payment for cardiology services would also have a severe impact on the infrastructure we have built up over the years to treat the number one killer in America today - heart disease.

Saint Thomas Hospital is not a specialty hospital. This hospital has no private investors or physician owners. There is no opportunity for our hospital to steer either away or towards a selected population of patients other than by offering high quality services with compassion and expertise. The inpatient reimbursement changes proposed will make our facility the unintended victim of the otherwise laudable goals of improving payment methods and reducing the steerage of unprofitable referrals.

We respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the validity and equity of the proposed payments. If Specialty Hospitals

with physician ownership are to be targeted, then we also request that special attention in the final analysis be given to non-specialty hospitals harmed by targeted reductions to ensure equity in the redistribution of payment among other services. Additionally, severity adjusted DRGs should not be implemented until the technology costs incurred by hospitals can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

Les Donahue
President and CEO
Saint Thomas Hospital

c. AHA: dlloyd@aha.org (Danielle Lloyd)

c. Bill Frist
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WASHINGTON DC 20510
(202) 224-3344
http://frist.senate.gov/index.cfm?FuseAction=AboutSenatorFrist.ContactFo

c. The Honorable Lamar Alexander
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148

Jenny Jasbir Multani M.D.
Washington Neurosurgical and Medical Group Inc.
1900 Mowry Avenue, Suite 406 • Fremont, CA 94538
Phone: 510.797.8160 • Fax: 510.797.8164

June 8, 2006

CMS
Dept of Heath & Human Srvcs.
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

Please find below my comments on the X STOP IPD.

1. Useful device for Lumbar Stenosis particularly stenosis limited to one to two levels.
2. Useful in patients who may not tolerate general anesthesia, as this device can be placed under local anesthesia.
3. Useful as it limits hospital stay as the devicew can be inserted as an outpatient basis.
4. We will have utility in treating mild to moderate stenosis as an initial step before doing extensive decompression surgery, with radiographic mild to moderate stenosis; XSTOP would be a useful initial step in some very symptomatic patient subsets.

Sincerely,

Jasbir Multani, MD

Cc:
St. francis Medical Technologies
CMS Comments
960 Atlantic Avenue, Ste. 102
Alameda, CA 94501

149

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Craig A. Beard, M.D.
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John T. Burch, M.D.
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Phillip J. Singer, M.D.
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Keith D. Morrison, M.D.
Diplomate
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Board Certified in Surgery
of the Hand (CAQSH

WESTERN KENTUCKY ORTHOPAEDIC ASSOCIATES®

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Gregg A. Malmquist, M.D.
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June 9, 2006

Dept. of Health & Human Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850
Attn: CMS-1488-P

RE: X-Stop IPD

To Whom It May Concern:

The X-Stop intraspinous decompression device is a welcome addition to my practice in treating patients with spinal diseases, specifically, spinal stenosis.

As I am sure you are aware, this is a device indicated for patients aged 50 or greater with spinal stenosis who have failed conservative measures and are facing more onerous surgical procedures. The device application is performed under a local anesthetic. In my case, I used the addition of intravenous sedation with this.

This device has been a Godsend for patients who, for whatever reason, cannot withstand a much larger operation. Most specifically, this device has benefited patients who have significant comorbidities including cardiothoracic problems, specifically COPD or coronary artery disease.

Additionally, patients without these significant comorbidities would rather have a less invasive procedure to obtain satisfactory improvement of their condition. This is certainly a natural inclination. The X-Stop IPD device fits that category very nicely.

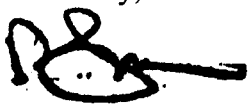
While I only have clinical experience for a short duration with this particular device, the patients I have used it on have benefited tremendously in a very short time. They have gone from being able to walk only about their homes and short distances to more extensive distances with much less pain and have greater functionality. The use of the

device affords the ability of placement just under local anesthetic in what could be an outpatient setting with little risk to the patient and a great deal of benefit. This quite simply fits a large portion of the population who face the decision between being active and functional versus undergoing a very large operation in order to achieve that goal. This is a much smaller procedure that gives marked improvement in functionality. It is a welcome addition to my practice.

This letter is written in support of this device, and a testament to, at least early, very satisfactory clinical success.

Any information regarding my opinion of this device can be requested from me at the above address.

Sincerely,



Phillip J. Singer, M.D.

Cc: St. Francis Medical Technologies

150

Patient Financial Services

Kettering Medical Center Network℠

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

On behalf of Kettering Medical Center Network, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the FY'07 Medicare Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 *Federal Register*. Given the complexities of CMS' proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on our health system, we are writing to urge you to carefully consider the following:

1. **One-Year Delay:** A one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology.

2. **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

3. **A New Classification System Only if the Need Can Be Demonstrated:** We do not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

4. **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

5. **Three-year Transition:** any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and our hospitals.

Kettering Medical Center Network supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a DRG system that more accurately reflects the costs of providing inpatient services. We recognize that your agency has taken these steps to make payments fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. Restructuring the DRG system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals.

As such, we strongly urge CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights. The additional time will allow Kettering Medical Center Network and other hospitals to more thoroughly evaluate the proposals and offer constructive feedback.

Again, thank you for the opportunity to share our comments on the DRG provisions of the proposed IPPS rule.

Sincerely,

Larry Zumstein
VP of Patient Financial Services and Contract Management
Kettering Medical Center Network

Larry Zumstein, Vice President of Patient Accounts, Kettering Medical Center Network, KMCN Administrative Support Building, 2110 Leiter Rd. Miamisburg, OH 45342 937-384-4831, Larry.Zumstein@kmcnetwork.org

151

CASTLE ORTHOPAEDICS & SPORTS MEDICINE, S.C.

Thomas R. Huberty, M.D. • Paul F. Witt, M.D. • Scott M. O'Connor, M.D. • Suresh Velagapudi, M.D.
Thomas J. McGivney, M.D. • Steven A. Marciniak, M.D. • Arif Saleem, M.D. *
Board Certified Orthopaedic Surgeons

June 5, 2006

CMS Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

To Whom It May Concern:

I am writing in request for approval and to preserve the financial viability of the X-stop Program. I have recently, back in February, gone to the training course for the X-stop medical device, the intraspinous distraction device. I have used it in five patients with excellent success. I have avoided large operative procedures. I have avoided all extended hospital stays. I have discharged every patient within hospital day number one. I have received excellent clinical results as well as excellent healing and patient satisfaction. I have unfortunately not been paid for any of the operative procedures to date, and these patients are quite stressed that their insurance companies and Medicare are not paying for these procedures.

Obviously in patients who are elderly with multiple medical problems, being able to provide medical treatment for spinal stenosis that does not necessitate large operative incisions, large amounts of postoperative blood loss, and the risks of spinal injury has benefits to the patient population. The benefits in cost to insurance companies as well as the government is staggering. The difference between a one-level X-stop device implanted with the patient discharged on postop day number one versus a large laminectomy, foraminotomy, partial fasciectomy, and instrumented fusion for a grade 1 degenerative spondylolisthesis, which is the standard of treatment, is staggering.

I believe that X-stop device will and indeed is filling a niche in my clinical practice for patients with one and two-level spinal stenosis with grade 1 or less spondylolisthesis. This is a viable surgical option in the patients that I have done so far. I have had nothing but positive responses to surgery. I have had nothing but positive responses to postoperative rehabilitation and postoperative pain with these patients that it has become my number one choice for these patients. Unfortunately, if I am not able to receive compensation for this device and it is going to fall on the patients to compensate for these devices, then unfortunately I will have to stop implanting them and that is going to be a detriment to our patients.

I hope you take these comments into consideration. I think personally this is the best device that has come on the market for treatment of spinal pathology in the last 30 years.

Sincerely,

Thomas J. McGivney, M.D.
Castle Orthopaedics & Sports Medicine, S.C.

TJM:jr

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* Board Eligible

152

Georgetown
University
Hospital
MedStar Health

Department of Neurosurgery

June 5, 2006

RE: CMS-1488-P
DRG's NEUROSTIMULATORS

To Whom It May Concern:

I am the Director of Movement Disorder Surgery at Georgetown University Hospital. In this capacity I have seen the profound impact that Deep Brain Stimulation has to change the quality of life of a patient suffering from a debilitating movement disorder. I have had patients who have been wheelchair bound that now are able to walk again after deep brain stimulation therapy. I have had patients who were able to feed themselves for the first time ever in their lives after surgery. I had a thirty five year old man who was being fed through a feeding tube in a nursing home be able to leave the nursing home, have his feeding tube removed, and return to work as a successful contributor to society.

Deep Brain Stimulation is a time consuming venture and it is the most technically demanding operation that I perform as a Neurosurgeon. When we do DBS surgery at our institution it is not unusual that the success of the operation will be dependent on the efforts of 20 to 30 individuals that represent my team. These surgeries require hours of planning that is not currently reflected in the current reimbursement scheme. It is not unusual for a Deep Brain Simulation electrode implant surgery to take 5-8 hours of my time.

With the expiration of the New-Tech Add-On Payment, we are concerned that full-system Kinetra implants will be inadequately paid in their current DRG's, 001 and 002. It is my opinion that unless this therapy is moved into a clinically coherent DRG which adequately reflects the cost associated with a full system Kinetra implant, financial barriers will impact our ability to provide this life changing therapy to Medicare patients that desperately need our help.

3800 Reservoir Road, NW, Washington, DC 20007-2113
phone: 202 444 4972 • *fax:* 202 444 7344

Georgetown
University
Hospital
MedStar Health

Department of Neurosurgery

In the proposed inpatient rule, published on April 25, 2006, CMS acknowledged that the average charges for full-system Kinetra cases in DRG 001 are comparable to cases in DRG 543, however, they proposed no change for FY07. We encourage CMS to move full-system Kinetra cases into DRG 543 in FY07 given the similarity of resource consumption.

CMS also proposed implementation of consolidated severity adjusted DRG's in FY08 or earlier in the proposed inpatient rule. However, severity-adjusted DRG's do not account for technologies such as Kinetra. We encourage CMS to make the appropriate adjustments for innovative technologies such as Kinetra to consolidated severity-adjusted DRG's before implementing them.

Sincerely,

Christopher G. Kalhorn
Assistant Professor of Neurosurgery
Director of Movement Disorders Surgery
Georgetown University Hospital
Washington, DC

3800 Reservoir Road, NW, Washington, DC 20007-2113
phone: 202 444 4972 • *fax:* 202 444 7344

153

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Charles N. Kahn III
President

June 12, 2006

VIA HAND-DELIVERY

Hon. Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1488P; CMS Proposed Rule with Comment Period, Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Federal Register (April 25, 2006)

Dear Dr. McClellan:

The Federation of American Hospitals ("FAH") is the national representative of privately owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching, short-stay and long-term care hospitals in urban and rural America, and provide a wide range of ambulatory, acute and post-acute services. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule ("Proposed Rule" or "NPRM") regarding changes to the hospital inpatient prospective payment system and fiscal year ("FY") 2007 rates. Attached as Exhibit A to this letter, FAH has set forth a list of all major issues commented upon in this letter (and the corresponding page number where discussion of each issue begins).[1]

II.C.2 HSRV WEIGHTS

CMS proposes to replace the existing charge-based establishment of DRG weights with a cost-based approach using a hospital-specific relative value system. CMS solicits comments concerning this new methodology to establish DRG weights and the process for a transition from

[1] Please note that FAH has attempted to use the numbering system utilized by CMS in presenting the NPRM in the April 25, 2006 Federal Register, at least with respect to major topic headings (e.g., II.C, IV.A, IV.M, etc.). Therefore, the section numbering will not be consecutive.

the current system. The FAH supports the establishment of DRG weights with a cost-based approach but recommends that CMS delay implementation of such a system by one year in order to work with hospitals to address payment accuracy concerns and methodological problems, then to transition hospitals to such an approach over an extended period to minimize the effects of implementation issues, unforeseen errors in methodology and to assess whether payment accuracy has been achieved without the need for broad changes in the patient classification system, such as the proposed consolidated severity adjusted DRGs. If CMS chooses to proceed with implementation in FY2007, it should ensure better payment accuracy than is achieved through its proposed or the existing methodology, and, at a minimum, correct the Proposed Rule's broad methodological errors used to develop the weights, address errors in the computation of hospital-specific relative values at the cost center level, and to the extent it proceeds with severity of illness adjustments to the patient classification system, selectively adjust a limited set of DRGs similar to what was done with cardiac DRGs last year. We address each of these concerns below.

1. **The Proposed Payment System Revisions Do Not Improve Payment Accuracy.**

The FAH is concerned that the proposed HSRVcc weights do not appear to significantly improve payment accuracy over current charge-based DRGs. MedPAC, in its Report to Congress: Physician-Owned Specialty Hospitals, presented its finding on payment accuracy in Figure 4, page 37. MedPAC illustrated that payment accuracy for its proposed hospital-specific relative weights was 25%, 49% and 26% for payment to cost ratios below 0.95, between 0.95 and 1.05, and above 1.05, respectively. The FAH engaged The Moran Company ("Moran") to replicate the CMS proposed DRG refinements.

Moran determined that payment accuracy for HSRVcc is very similar to MedPAC's recommendation for hospital-specific relative weights only (not including MedPAC's cost-based weight proposal). *See* Report of Moran Company (Exhibit B). Moran's analysis establishes that the CMS proposal results in accuracy of 23%, 48% and 28% for payment to cost ratios below 0.95, between 0.95 and 1.05, and above 1.05, respectively. These results from CMS's proposed methodology are very similar to MedPAC's results for its recommended refinement for hospital-specific relative weights. However, MedPAC also recommended that DRG refinements include the adoption of cost-based weights. While CMS has called its refinement Hospital-Specific Relative Value cost center ("HSRVcc") method, it does not produce the payment accuracy MedPAC produced with the combined hospital-specific relative weights and cost-based weights. While MedPAC did not report the combined payment accuracy of hospital-specific relative weights and cost-based weights, it is clearly evident from Figure 4 in its Report to Congress that most of the payment accuracy was achieved by the cost-based weight refinement. The MedPAC report identifies the combined impact of hospital-specific relative weights, APR-DRG and cost-based weights. But as can be seen from Figure 4, the addition of APR-DRGs to hospital-specific relative weights changes payment accuracy very little from using only hospital-specific relative weights. Figure 4 shows that payment accuracy for hospital-specific relative weights plus APR-DRG produced payment accuracy of 27%, 53% and 20% for payment-to-cost ratios of below 0.95, between 0.95 and 1.05, and above 1.05, respectively. As can been seen from these numbers, there is little improvement with the addition of APR-DRG. There was a slight increase in accuracy for above 1.05 but a decrease in accuracy for below 0.95. But when cost-based

weights were added, payment accuracy improved significantly. Figure 4 shows that with the addition of cost-based weights payment accuracy improves to 12%, 73% and 15% for below 0.95, between 0.95 and 1.05, and above 1.05 respectively.

As can been seen from this analysis, the CMS proposal for HSRVcc fails to come close to the payment accuracy produced by the MedPAC recommended refinements. Thus, CMS needs to develop a system that more closely achieves the results MedPAC was able to achieve through its recommendations. Achieving such a result may obviate the need for more drastic changes such as consolidated severity DRGs. It makes little sense to transition from a charge-based DRG system to a system that achieves no better payment accuracy, as proposed by CMS. Thus, CMS should delay the beginning of any such transition by one year to develop a system that achieves meaningful results.

2. Broad Methodological Errors Used to Develop Weights.

a. Derivation of Mean National Cost to Charge Ratios.

CMS has hospital-weighted rather than charge-weighted the calculation of the geometric mean cost to charge ratios (CCR or CCRs) for each of the 10 cost centers that are used to scale the charge-based weights. These averages are unweighted and therefore do not account for the varying amount of Medicare charges each hospital contributes to total charges. Consequently, very small hospitals individually have just as much impact on the mean CCRs as larger hospitals, and hospitals with low charges (high CCRs) have just as large an impact as hospitals with high charges (low CCRs).

Mathematically, the only correct way to get from total hospital charges to total hospital costs is to use a charge-weighted average of the hospital CCRs. Applying these unweighted ratios to charges does not produce an accurate estimate of the national average cost per case. A comparison of the two different methods indicates that on an actual basis, CMS's decision not to charge-weight the calculation of the geometric mean CCRs over weights routine and ICU costs and under weights ancillary costs. In real terms, the failure to use charge-weighting in the calculation of the geometric mean CCRs exaggerates the shift in payments that occurs from the use of cost-based DRGs.

The FAH agrees with the many other comments on this issue that mathematical logic would suggest that CMS should recalculate the mean national CCRs using a charge-weighted method. FAH further recommends that CMS evaluate work performed by The Moran Company for FAH suggesting that payment accuracy improves when the DRG weights are neither charge-weighted nor trimmed (as discussed below), but instead are weighted by cost at the department level. When The Moran Company evaluated payment accuracy using department level cost based weights, payment accuracy was 10%, 75% and 15% for payment to cost ratios below 0.95, between 0.95 and 1.05, and above 1.05, respectively.

b. Computation of CCRs from Individual Hospital Cost Reports.

CMS describes a process at 71 Fed Reg. 24010 wherein it developed CCRs for each of 10 cost centers at every hospital where such cost center was included in its data base. However, CMS notes "We... removed any cost center CCRs where the log of the cost center

CCR was greater or less than the mean log plus/minus 1.96 standard deviations of the log of that cost center CCR." This trimming excludes 260 large hospitals that account for 25 percent of routine accommodation charges, yet the charges for these hospitals are included in calculating the DRG weights. The result is a significant mismatch between the CCRs and the pool of charges to which they are applied. A review of the CCRs for these hospitals suggests they are predominantly correct. Thus, it seems anomalous that these hospitals CCRs are excluded from the calculations. CMS uses trim points of three standard deviations to trim data for other purposes under this rule. For example at 71 Fed. Reg. 24008, CMS describes the methodology that it uses to aggregate the claims data forming the basis of cost-based weights. In referring to how it would "Clean the Data", CMS indicates that three standard deviations are used. Using three standard deviations in this instance returns the data for routine accommodation charges to a normal distribution. Mathematical logic would suggest that CMS should use three standard deviations to trim the cost center CCRs. However, as noted above, the FAH recommends that CMS evaluate this issue further in light of evidence from The Moran Company that payment accuracy improves when the weights are neither charge-weighted nor trimmed but instead are weighted by cost at the department level. When The Moran Company evaluated payment accuracy using department level cost-based weights, payment accuracy was 10%, 75% and 15% for payment to cost ratios below 0.95, between 0.95 and 1.05, and above 1.05, respectively.

c. Organ Acquisition Costs

It is our understanding that organ acquisition charges were included in the calculation of the transplant DRG HSRVcc weights. Organ acquisition costs are reimbursed by the Medicare program on a cost basis. Thus, the inclusion of organ acquisition charges in the computation of the transplant DRG HSRVcc weights improperly overstates such weights. The FAH recommends that CMS remove the organ acquisition charges from the computation of the transplant DRG HSRVcc weights.

3. Errors in the Computation of HSRVs for Each Cost Center for Each DRG in NPRM Part II.C.2.b Table A, 68 Fed. Reg. at 24008-09.

Table A, pertaining to "Charge Line Items from MedPAR Included in Cost Center Charge Group" appears to contain several inconsistencies. The FAH requests that CMS clarify precisely where specific items should be included. Generally, the FAH notes that the MedPAR charge descriptions do not match the FORM CMS-2552-96 Cost Center description(s) for several cost centers. For example:

(a) MedPAR lists (18) Lithotripsy Charges where the cost reporting form lists Radioisotopes;

(b) MedPAR lists (6) Other Services where the cost reporting form lists Whole Blood and Packed Red Blood Cells;

(c) MedPAR lists (19) Cardiology Charges as including line 54 of the cost report, which is Electroencephalography;

(d) MedPAR lists (16) Blood Administration Charges where the cost reporting form lists ASC (Non-Distinct Part);

(e) MedPAR lists (24) Outpatient Services Charges where the cost reporting form lists Emergency;

(f) MedPAR lists (25) Emergency Room Charges where the cost reporting form lists Ambulance Services;

(g) MedPAR lists (26) Ambulance Charges where the cost reporting form has Renal Dialysis;

(h) MedPAR lists (29) ESRD Revenue Setting Charges where the cost reporting form lists Clinic;

(i) MedPAR lists (30) Clinic Visit Charges where the cost reporting form has Other Outpatient Services, Other Ancillary, Home Program Dialysis and Ambulance Services;

(j) Ambulance services appear to be included twice, once in (30) Clinic Visit Charges and once in (25) Emergency Room Charges;

(k) Lithotripsy is included in Cardiology Charges, which seems odd since it is not a cardiology service, at least not typically;

(l) Line 62 "Observation Beds" is not reflected separately in Table A. In situations where there is no distinct observation area, this cost would be included in the Routine Cost Center. In situations where there is a distinct observation area, the cost is not picked up since on the cost reporting form, the cost is recorded on Line 62.01. The FAH believes that Lines 62 and 62.01 should be included in Other Services and Charges and that Line 102 "Less Observation Beds" of the cost report should be included in the Routine Cost Center to avoid duplicating observation costs;

(m) Line 68 "Other Reimbursement" of the cost report is not listed in the Table at all. Other Ancillary on Line 59 of the cost report is reflected in (30) Clinic visit charges. In actual practice, on the cost report, this line is subscripted into various cost centers such an MRI, Cardiac Catheterization, Lithotripsy and others.

While these inconsistencies do not impact the conceptual basis of the use of HSRVcc's, the inconsistencies between the forms and formats call into question the accuracy and validity of the crosswalk to the cost report from MedPAR charge descriptions. This could become important, FAH believes, as the amounts become greatly magnified in the transition

from a charge-based DRG system to a cost-based DRG system. The FAH requests, therefore, that CMS properly align these items prior to calculating DRGs under a cost-based system and furnish providers with appropriate revised forms as necessary with instructions regarding how to avoid duplications, omissions and/or other inaccuracies.

4. Transition Period.

CMS acknowledges that because of the dislocation of funding for services created by the use of cost-based DRG weights among hospitals, it may be appropriate to phase in the use of this new approach over a period of years. As indicated above, the FAH suggests a one year delay in implementation to give CMS an opportunity to develop a system that achieves payment accuracy in the range of that achieved through the MedPAC recommendations. Once such a system is developed, because of the significance of this change, there should be an extended transition, a minimum three-year phase-in period is appropriate. This would give CMS time to address any flaws in methodology that may be unforeseen at this point in time and allow individual hospitals to adapt to any severe dislocation of funding. This recommendation should be considered in conjunction with the FAH comments concerning consolidated severity adjusted DRGs, below.

C.3 DRGs: SEVERITY OF ILLNESS

CMS proposes that the current CMS DRG system be replaced with a severity based DRG system by FY 2008 (if not earlier). The proposed severity based DRG system was designed by 3M Health Information Systems, as modified by the proposed rule into a consolidated severity based DRG system, referred to hereinafter as "CSA DRG." The FAH offers comments concerning the proposed CSA DRG system in four areas: (1) the basis for the proposed system; (2) the proposed case mix index ("CMI") adjustment associated with anticipated hospital behavior under the proposed system; (3) the interaction between CSA DRG and outlier payments and other add-on payments; and (4) the implementation of a CSA DRG system.

1. Basis for the Proposed CSA DRG System.

The FAH strongly opposes any implementation in part or whole of the CSA DRG system for FY 2007. This opposition is based on (a) inadequate notice for informed public comment, (b) fundamental concerns of the proposed methodology and (c) insufficient information regarding the impact of the system. The FAH can only support a limited but targeted DRG expansion to achieve improved payment equity, as described below, until such time as meaningful study and debate can occur regarding a more ambitious effort.

a. Inadequate notice for informed public comment.

The FAH believes adoption of any aspect of CSA DRGs during FY 2007 would be inappropriate under any meaningful reading of the notice and comment requirements of the Administrative Procedure Act and the limitations of the Secretary's rulemaking authority. Since publication of the NPRM, FAH has requested the 3M report and underlying data that forms the basis for the proposed CSA DRG system. CMS advised the FAH and other participants in a

video conference on April 18, 2006, that the 3M report in question is in draft form and CMS would not provide draft information to the public. The courts have repeatedly held that the APA requires an agency relying on outside reports and data to make such reports and data available to the public so that informed comment can be provided to the agency and the courts have overturned regulations when such procedural irregularities have occurred. *See, e.g., Asarco, Inc. v. U.S. Environmental Protection Agency*, 616 F.2d 1153, 1156, 1163 (9th Cir. 1980) (agency outside consultant's report relied upon for rulemaking not provided for comment); *Marathon Oil Co. v. Environmental Protection Agency,* 564 F.2d 1253, 1264 (9th Cir. 1977) (failure to provide data relied upon for rulemaking for assessment by those affected by rule renders the rule procedurally invalid). It does not matter that the information in such a report is preliminary, or the report is in draft form, if the information or the report are relied upon by the agency as part of its decision making process, they must be made available to the public for comment. In this instance, the report from 3M constitutes the very basis for the proposed system and CMS appears not to have prepared any original work that would otherwise support the proposed system. Thus, without access to the 3M report and underlying data, no meaningful comment can be provided by the industry.

b. Concerns regarding the proposed CSA DRG system.

The FAH understands MedPAC's recommendations and CMS's proposal to move towards a DRG reimbursement methodology that is based on severity of illness. However, any such change must also appropriately reimburse providers for resources used to treat the Medicare patient population. The FAH refers CMS to its comments at page 2, above, indicating that MedPAC data suggests that severity based DRGs would have little impact on payment accuracy under a cost-based HSRV system of the type originally recommended by MedPAC. Until that system is appropriately implemented and its impact on payment accuracy is gauged, CSA DRGs seems premature and would create an unnecessary burden on hospitals. Also, based on the limited review thus far of the provided data, we believe some of the foundational items related to appropriate provider reimbursement have not been fully integrated into the system. An example of inadequate reimbursement is illustrated by comparing a current CMS DRG to the projected CSA DRG.

CMS DRG	CMS DRG Weight	CSA DRG	CSA DRG Weight
DRG 471 Bilateral or Multiple Major Joint Procedures of Lower Extremity	FY06 DRG 471 Bilateral or Multiple Major Joint = 3.1 and FY07 DRG 471 Bilateral or Multiple Major Joint = 2.	CSA DRGs do not recognize bilateral joint procedures. The weights for comparison are dependent upon which specific joint (for example, knee or hip)	Hip = DRG weight ranges from 1.8 - 2.5; Knees = DRG weight ranges from 1.7 - 2.5

As demonstrated, patients that are grouped into this CMS DRG are reimbursed at a higher weight based on CMS's calculation of the resources that it takes to care for this patient

population. There is no such "bilateral" joint DRG under the proposed CSA DRG system. We do believe that it is CMS's intent to appropriately reimburse the provider for services rendered; therefore, a new or different CSA DRG would need to be explored.

We believe there to be other examples within the proposed system that contain this apparent flaw in the underlying methodology, such as high cost drugs. We believe that this is due to the fact that APR-DRGs and thus CSA DRGs are based on severity of the patient's illness and not the underlying complexities that may affect treatment of that patient. The bilateral joint replacement is a prime example of this. The resources used to perform a bilateral joint replacement increase as the complexity of performing a bilateral replacement is greater than doing just one. We believe CMS recognizes these issues and we concur with CMS's statement in the Proposed Rule that a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system. The FAH applauds CMS's recognition of this in the area of technology. This concept needs to be fully explored and a solution provided prior to implementation of a refined system. FAH members welcome the opportunity to assist in the development of criteria to not only address technology complexities but other areas in which the patient's diagnoses, alone, will not adequately describe the complexity associated with the resources used to treat the patient.

Additionally, the FAH has found that the APR-DRG methodology, and therefore the CSA DRG grouping logic are in some cases, not consistent with official coding guidelines. An example of this is a patient with chest pain that is seen in the emergency department and because of prior cardiac history, is admitted to rule out myocardial infarction (heart attack). The physician had performed a cardiac catheterization on the patient the previous week and although some coronary artery disease ("CAD") was present, it was not significant enough for treatment or to be causing the chest pain. The physician documented the final diagnosis as "non-cardiac chest pain," with a secondary diagnosis of CAD.

The APR-DRG system makes an assumption that any case with chest pain with any other secondary diagnosis of coronary artery disease should be classified to the coronary artery disease DRG, as set forth below:

Original Case (classified correctly)	**Revised Case (inappropriate classification)**
786.59	786.59 414.01
(Note: 414.01 should be coded)	
APR-DRG 2031 Chest Pain – Minor	APR-DRG 1981 Angina Pectoris & Coronary Atherosclerosis – Minor

The APR-DRG grouper collapses the diagnoses and resequences the coronary atherosclerosis (414.01) as the principal diagnosis putting the case into an APR-DRG for coronary atherosclerosis instead of chest pain. The assumption by the APR grouper may be that the work-up of the patient and resource utilization was focused on ruling out a cardiac condition,

but any CMS classification system is used for a variety of purposes. It is inappropriate for a case to be clinically classified into a group that is in direct disagreement with the specific physician documentation concerning the reason for the admission. This example illustrates that more time is needed to fully explore and evaluate the proposed severity adjusted DRG methodology.

The FAH agrees with the concern expressed on the Open Door Forum on May 5, 2006, regarding the importance of maintaining transparency within the DRG system. Any methodology that is used for the Medicare patient must be readily available and cannot be based on a proprietary system. For example, how will future DRG refinements be made if the underlying system is owned by 3M? It seems that the hospital industry will be putting itself in the same position as it is in with the use of AMA's CPT coding system for outpatients.

The FAH understands that CMS is aware that the UB-92 is limited to nine specific form locators for ICD-9-CM diagnosis codes for billing; and that currently there is a variance between the number of codes submitted by hospitals via the electronic claim submission process and the number of codes processed by CMS. It is impossible to properly refine the DRG system using MedPAR data due to this restriction. The limitation of nine specific form locators for ICD-9-CM diagnosis codes will not present issues for cases with nine or fewer diagnoses. However, in the case of more than nine ICD-9-CM diagnoses, which are typically reported for the more-severely ill, this limitation will be problematic. It is our understanding that "overflow" (more than nine diagnoses) may be reported in the "remarks" field of the UB-92; however, it is uncertain as to the subsequent recognition of these codes within the payor system or within MedPAR for future data analysis. The FAH respectfully submits that an incremental step in working towards a refined methodology system is to have the CMS systems remediated to stop truncating the number of diagnosis and procedures codes that providers submit. It is essential that the number of diagnoses and procedures processed by Medicare be expanded beyond 9 diagnoses and 6 procedures. There is concern that any impact that is being projected today using MedPAR data is potentially flawed based on this system limitation.

We strongly agree with CMS's statement that a transition involving two groupers to blend payments with and without severity would be impractical and burdensome.

CMS also proposes as an alternative to a wholesale or partial implementation of CSA DRGs applying a clinical severity concept to an expanded set of DRGs in FY 2007. CMS states that the agency has received correspondence requesting that a clinical severity concept be applied to DRG 546. CMS mentions that it has taken steps to better recognize severity of illness among cardiovascular patients for FY 2006. CMS also states that they are considering whether a similar approach should be applied to select DRGs for FY 2007 and has requested comments on this alternative.

c. Specialty Hospitals

FAH cannot overstate its fundamental belief that while these DRG refinements were recommended by MedPAC and proposed by CMS primarily as a payment policy response to the documented problems of physician-owned specialty hospitals, they are inadequate for the purpose for which they are intended and no substitute for addressing the underlying conflict of interest issue that leads to patient selection and overutilitzation. The same

conclusion is true for other possible administrative solutions that CMS is considering amending in light of the physician-owned specialty hospital dilemma. These proposals do not address the economic issues that have led physician-owned specialty hospitals to avoid Medicaid and uninsured patients. As MedPAC noted in its March 2005 Report to Congress, opportunities for selection never fully disappear," because of hospitals advantages resulting from more sophisticated and accurate cost accounting data compared with Medicare and because "physicians always know more than CMS about individual patients' expected costs." In addition, there is a strong incentive for physician-owners to compensate for payment reductions from these DRG refinements by increasing the volume of procedures, particularly outpatient procedures and other tests not covered by the payment. The only effective policy response is for strict enforcement of existing self-referral and anti-kickback authorities to prohibit the conflict of interest inherent in physician ownership and self referral.

d. Recommendation

CMS should not adopt CSA DRGs during FYs 2007 or 2008. Instead, CMS should do no more than selectively adjust for patient severity a limited number of DRGs, similar to what was done with cardiac DRGs last year, and only for DRGs where CMS has data demonstrating that severity considerations will lead to more accurate payments consistent with resource use, such as may be the case with DRG 546 for FY 2007. For FY 2008, CMS could propose other specific DRGs where severity considerations would give rise to better payment accuracy and give the industry adequate notice to provide meaningful comments. Except for the mention of DRG 546, CMS has not provided any data or supporting or explanatory rationale upon which to make meaningful comment. Also, there is limited and inconclusive data available regarding the effects of last year's expansion. After CMS has data from a limited expansion of DRGs in FYs 2007 and 2008, CMS will be in a better position to determine whether wholesale severity based changes to the system are appropriate or whether it can achieve most of the intended effect of such a system through limited but targeted DRG expansion, or even whether such expansions are necessary in light of the payment accuracy achieved through cost-based weights. To the extent that CMS does expand the number of DRGs this year to accommodate severity concerns, the FAH requests that such expansion be announced through an interim rule with comment period.

2. <u>CMI Adjustments for Anticipated Hospital Behavior</u>.

In the Proposed Rule, CMS has solicited comments on the potential for changes to the CMI from a new DRG system. More specifically, CMS states its belief that the adoption of CSA DRGs would create a risk of increased aggregate levels of payment as a result of increased documentation and coding. CMS cites the MedPAC recommendation for the Secretary to project the likely effect of reporting improvements on total payments and make an offsetting adjustment to the national average base payment amounts. CMS has reiterated its position that section 1886(d)(3)(A)(vi) of the Act gives the Secretary broad discretion to adjust the standardized amount so as to eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix.

The FAH believes that any behavioral offset to the standardized amount to attempt to adjust for increased documentation and coding is unnecessary and unwarranted. While CMS has

solicited comments on the potential behavioral offset to the standardized amount for FY 2007, CMS has not provided any analysis to justify or support the need for a behavioral offset, including the fact that no specific offset amount has been proposed. The FAH believes that prior to any behavioral offset being implemented, CMS is obligated to provide adequate notice and an opportunity to meaningfully comment in response to a specific proposal that is supported by an analytical basis and data for any such offset.

The FAH is not convinced that a behavioral offset can be objectively quantified and thus believes that any behavioral offset is unnecessary and unwarranted. Trying to objectively quantify coding changes by separating real coding from possible improved coding and documentation is virtually impossible. Claims are coded using official standard coding guidelines which would be the same regardless of what DRG system is used to group patients. To attempt to say a claim has been or would be coded differently under a change to the CMI is contrary to adherence to standard coding guidelines. Current coding practices require that a claim be coded completely and accurately. This "complete and accurate" approach is consistent with the Health Information Management/coding professionals' code of ethics. HIM professionals understand the importance of coded data and simply do not code strictly for the purpose of reimbursement. Where the standard coding guidelines have not changed and such standard guidelines are applied to claims, the FAH believes that it would be inappropriate to apply a reduction to the standardized amount for perceived improved documentation and coding.

Historically, the annual update to the IPPS standardized amount is reviewed by Congress with recommendations from MedPAC. Such updates take into consideration all the factors that drive hospital IPPS payments, including coding changes. While profit margin is not the single controlling factor in the update process, profit margin analysis is nonetheless a vital part of the update process. In its Report to Congress: Medicare Payment Policy dated March 2006, MedPAC presented that hospital overall profit margin for 2004 was -3.0% and profit margin was projected to be -2.2% for 2006. With Medicare profit margins below zero for the average hospital, there is no support that hospitals are benefiting from any prior perceived improvement in documentation and coding. Congress, with MedPAC's update recommendations, has effectively eliminated any potential benefit from improved coding. The FAH believes that the update process that considers the overall performance of hospitals is a much more objective means of addressing any perceived improved documentation and coding than can be achieved by a guess estimate of improved coding. Thus, the FAH is convinced that the update process adequately and appropriately adjusts for any improved documentation and coding.

3. Cost Based Weights: Outlier Threshold, NPRM Part II.C.4 and Other Payment Adjustments.

CMS indicates that it has yet to complete an analysis of a MedPAC recommendation for DRG specific outlier thresholds that are financed by each DRG and that such proposal would require a change in the law. In a similar vein, CMS notes that a severity based DRG system would, to some extent, eliminate many cases that currently are paid on an outlier methodology, because many former outlier cases would receive higher payments as a type 3 or 4 DRG under such a system. CMS also notes that 3M has modeled outlier payments under cost and severity based DRGs indicating a projected outlier threshold of $18,758. Unfortunately, neither the 3M report nor its data have been provided to the public so that informed comment regarding outlier

payments can be provided. It is impossible to determine from the scant information provided in the Proposed Rule whether such an outlier system also would require a change in the law.

Indeed, Table J, a payment impact table at 71 Fed Reg. 20024, which seeks to inform the public how the proposed CSA DRG system would shift Medicare funds throughout the hospital industry based on type of hospital, does not even seem to take outlier payments into account. Given that outlier payments represent 5.1% of total DRG payments, this would suggest that Table J may not accurately represent such payment shifts.

Until the Secretary can ascertain what if any changes will need to be made to the outlier payment system to account for implementation of a CSA DRG system, and provide the industry with meaningful notice and data to comment, the implementation of severity based DRGs is premature.

MedPAC, as part of its package of recommended DRG refinements called for a revision in the way outliers payments are funded. Presently, outlier payments are funded in a manner tantamount to a "flat tax" -- all DRG payments are reduced 5.1% regardless of whether or how many outlier cases occurred under a particular DRG. MedPAC recommended, however, that outlier funding operate more like a "user tax" – the weights assigned to specific DRGs where outlier cases occur would be adjusted as necessary to create a 5.1% outlier pool. MedPAC findings demonstrated that payment accuracy improved with a DRG-specific funded outlier policy. However, as is true with the other refinements, the DRG specific outlier policy, which requires Congressional action, would also result in redistributions across hospitals. FAH recommends that CMS study the MedPAC outlier recommendation as part of any severity refinements and ascertain the appropriate outlier funding set aside as part of such severity refinements. The FAH believes that the 5.1% set aside to fund outlier cases can be significantly reduced with the adoption of DRG refinements that improve payment accuracy. Reducing the outlier pool could also provide an important counterbalance against the redistributive effect across hospitals that would occur with the implementation of DRG refinements.

Similarly, at 71 Fed. Reg. 24006, the Secretary states that: " We note that MedPAC's recommendations with regard to revising the DRGs to better recognize severity of illness may have implications for ... the IME and DSH adjustments. We will discuss these implications in more detail in the following sections." Unfortunately, while outlier and case mix are discussed by the Secretary, the only further discussion of the IME and DSH implications of the proposed system occur 21 pages later with the statement that "further study is warranted." *Id.* at 24027. Such statements cannot form the basis for meaningful comment when the nature of such "implications" is not identified in the Proposed Rule. The FAH certainly does not believe that either IME or DSH adjustments are or should be affected by CSA DRGs. The new system is designed to be budget neutral as compared to the CMS DRG system and payment adjustments for IME and DSH are in addition to the DRG payments.

Indirect medical education payments are part of a proxy for capturing the indirect costs of care in a teaching hospital such as, for example, increased medical records costs or additional diagnostic tests ordered by resident in a training program that may not be ordered by a practicing physician. Neither CMS DRGs nor CSA DRGs are designed to reimburse hospital specific costs nor are they calculated to build in these teaching related costs at a facility specific level.

Additionally, severity cannot be linked to such costs. Similarly, DSH payment adjustments are not calculated with regard to factors solely related to Medicare beneficiaries. Rather, one focus of DSH payments is on low income Medicaid patients. The history of the DSH provisions suggests that Congress recognized that hospitals treating a large volume of low income patients had a sicker, more cost intensive patient population than other hospitals and DRG payments did not compensate for those facility specific costs incurred by such hospitals on a disproportionate basis. DSH House Report, 1985 U.S.C.C.A.N. at 594 (noting that treating low income patients, including Medicaid patients, indirectly increases the cost of treating Medicare patients because of the need for "extra over-head costs and higher staffing ratios which reflect the special need for such personnel as medical social workers, translators, nutritional and health education workers ...."). Over time, the purpose of DSH payments has evolved to being necessary for Medicare to share in the payment for low income, uninsured individuals in order to maintain access to health care services for Medicare patients. Secretary Thompson in his letter of February 19, 2004 to the American Hospital Association transmitting the CMS "Questions On Charges For The Uninsured" acknowledged this evolution when he states "Medicare and Medicaid have a long history of doing their part to help the uninsured that includes paying hospitals $22 billion each year through the disproportionate share hospitals provisions to help hospitals bear the cost of caring for the poor and uninsured." Additionally, MedPAC recognized a similar purpose to DSH payments in its March 1998 Report To Congress: Medicare Payment Policy, Volume 1, Chapter 6 at 65 and again in the March 1999 Report To Congress: Medicare Payment Policy, Chapter 3, pages 60ff. Neither of these additional payments are related to case severity and nothing is inherently built into CSA DRG payments that would compensate for either of these factors, especially given that CSA DRGs are designed to be budget neutral as compared to CMS DRGs.

4. <u>Implementation</u>.

In addition to the lack of information regarding implementation of an outlier system that would function consistent with existing law, as addressed above, there are other issues that flow from a wholesale redesign of the DRG system that also are not addressed in the NPRM. Some areas that will require analysis by CMS before severity based DRGs can be implemented include:

a. *Transfer DRG Provision*: The approach to the transfer provision under a refined DRG system, including both methodology and payment impact, must be fully disclosed with appropriate notice to allow for adequate review and public comment;

b. *Lack of Historical Data*: There will be a loss of trending DRG data for CMS and for all associated stakeholders. This will include an evaluation of how, or if, the OIG will have the ability to examine DRGs that have a history of aberrant coding to determine if additional hospital specific follow up will be performed;

c. *Impact on Post-Acute Settings using CMS DRGs*: CMS needs to consider and examine how the proposed new DRG methodology, if adopted, would impact post-acute settings that use the current CMS DRG as a basis for the reimbursement (including psychiatric and long term care hospitals).

d. *Renegotiation of open Corporate Integrity Agreements (CIA)* – Since many coding related CIAs are designed based on CMS DRGs, the terms of any such agreement will have to be revised. Requiring providers under a CIA to use a dual system is unreasonable.

CMS should carefully consider whether there are viable alternatives to CSA DRGs. For example, CMS should evaluate whether migration to a new coding classification system, ICD-10-CM and ICD-10-PCS, would provide the greater benefit in achieving a severity adjustment reimbursement methodology. Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to ICD-10) were developed as replacement classification system.

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in the committee language for the Medicare Modernization Act, recommended that the Secretary of Health and Human Services (HHS) undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology as required under the 2000 Benefits Improvement and Protection Act. To date, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that without a change to ICD-10 soon, there could soon be a significant data crisis in the U.S. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule, such that if a final rule requiring the implementation of ICD-10 is announced as part of the FY 2008 rulemaking, implementation of that part of the rule would take place beginning in FY 2010.

The FAH urges CMS to consider the impact of educating, preparing for and adopting severity adjusted DRGs and then a year or so later having to reeducate and prepare for ICD-10 and then to learn the DRG methodology utilizing ICD-10. There appears to be a great deal of duplicative and unnecessary overlap for what may turn out to be limited benefit.

The Federation opposes global change to a severity adjusted DRG system until a more robust and thorough analysis can be performed and appropriate informed comments submitted. Providers require more than a 60 day comment period to perform a thorough analysis. If CMS is planning on beginning the severity adjusted DRG methodology for FY 2008, all information must be made available at least a year in advance of a planned implementation. This needs to include the availability of the CSA DRG grouper for an extended period of time. This should be readily available and should allow for the submission of "batch claims" rather than a case by case grouping, which is currently available on CSADRGASSIGN. Any consideration for the design of a Medicare reimbursement system must be in the public domain and should not be proprietary.

The FAH strongly recommends the development of a task force/technical committee to help with considerations of a refined DRG methodology. The FAH agrees that revisions should be considered, but this should be done through a formalized open-door task force with experts from both the clinical and financial segments of the industry. It is also our recommendation that individuals that participated in the Maryland Demonstration Project for DRGs be included on the

task force to ensure that their experience with implementation is considered and addressed. Based on comments made during the Open Door Forum, it appears that there were implementation concerns with that demonstration project. As part of this task force, the FAH also suggests analyzing situations in which the complexity of the patients are not always appropriately captured (for example, new technology).

Finally, CMS needs to carefully evaluate the regulatory environment to understand the burden being placed on providers and on CMS resources based on the substantial items being proposed and/or implemented. This includes the move to UB04, the NPI, the 5010 upgrade, and the MACs. All of these initiatives independently have a risk of disruption of payment; however, when these initiatives overlap, this risk increases exponentially.

II.D. DRG RECLASSIFICATIONS

As CMS outlines in the NPR, there are a limited number of proposed changes to specific DRG classifications. The FAH comments regarding those proposed changes, and requests for additional changes, are set forth below.

1. Pancreas Transplants.

The FAH agrees with the proposal for pancreas transplants (DRG 513) to remain in the pre-MDC. We are pleased with CMS's willingness to review this DRG grouping based on proposed NCD changes to ensure consistency throughout the system.

2. MDC 1 (Diseases and Disorders of the Nervous System).

a. *DRGs: Neurostimulators.*

The FAH agrees with the CMS proposal to eliminate the add-on payment based on new technology guidelines. However, the limited data based on the short time frame between new code creations, add-on payment, and the use of charge data does result in difficulty in recalibrating the DRG to ensure appropriate reimbursement. Based on the data presented by CMS, it appears that neurostimulators do have an increase in associated charge, but it is unknown if any variance is due to hospital mark-up or due to the cost of the device. The FAH recommends that this be assigned to DRG 543 to account for discontinuation of the add-on payment for this advanced technology for Medicare beneficiaries.

b. *DRGs: Carotid Artery Stents.*

The FAH recommends, based on the data currently provided with the 2007 Proposed Rule, the current DRG relative weight be recalibrated to take into consideration the charge associated with the carotid artery stents. FAH recommends that this be assigned to DRG 533 and 534 to account for the cost associated with provision of carotid artery stents.

3. MDC 5 (Diseases and Disorders of the Circulatory System).

a. *DRGs: Epicardial Leads.*

The FAH agrees with the recommended revisions to rectify the prior inconsistency. We support CMS' acknowledgement of the inconsistency in the coding classification system that will be corrected with updates on 10-01-06.

b. *DRGs: MCVs and Defibrillators.*

Based on the information presented in the proposed rule, the FAH agrees with the recommendation to not sub-divide DRGs 515, 535 and 536. The FAH requests a summary from CMS in the final rule to address if the expected outcome was achieved as a result of the creation of the cardiac clinical severity DRGs (DRG 547 through 558), effective October 1, 2006.

4. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue).

a. *DRGs: Hip and Knee Replacements.*

The FAH agrees with the proposal to remove those procedure codes from DRG 471 that do not represent bilateral and multiple joint revisions or replacements. However, a question still remains in the case of a patient who may have a joint revision performed on each leg that would constitute a bilateral joint revision yet, based on the current coding classification cannot be readily identified.

b. *DRGs: Spinal Fusion.*

The FAH agrees that it is premature to consider splitting the spinal fusion DRGs into potentially up to 10 new DRGs, at this time. There is a need for additional data analysis prior to recommending new DRGs. Similar to what we requested with regard to the FY06 cardiac DRGs, the FAH requests a summary from CMS in the final rule to address if the expected outcome was achieved as a result of the creation of the spinal DRG 546, effective October 1, 2006.

5. DRGs: CHARITE ™

The FAH agrees with the recommendation to not re-assign CharitеTM at this time.

6. DRGs: Severe Sepsis.

The coding professionals within FAH agree that there is continued and ongoing confusion associated with the coding of sepsis, severe sepsis, and SIRS with and without organ dysfunction. There is concern that the ongoing changes have contributed to industry wide confusion versus providing clarification and certainly are not consistent with physician documentation patterns. There is a reference to the code modification that will be made part of the October 1, 2006 coding update; however, the changes specified in Table 6E, Revised Diagnosis Code, do not provide sufficient information to determine if this will decrease confusion. In the review of the minutes from the September 29-30 C&M meeting, there were many options presented; yet the final determination is not known and will not be known until a

tabular addendum is published. At this point, it will be a matter of waiting to see if the diagnosis revisions alleviate the confusion associated with these conditions.

In this section, there is also a reference made to updated coding guidelines that will be published over the next year which could begin the process of improving data for this group of patients. The FAH proposes that a new process be considered related to the development and deployment of establishing or updating official coding guidelines. The fact that CMS has become more "provider friendly" has been duly noted and is appreciated. The open door forum concept is a great example of offering an opportunity for CMS to provide education on industry topics as well as offering the provider community the opportunity to ask questions or provide insight into areas of concern or confusion. This same concept needs to be applied to the development of official coding guidelines. The FAH requests an open meeting to discuss potential coding guideline changes to ensure that the advice being considered is operationally sound and applicable in the real world.

The Editorial Advisory Board (EAB) would obviously still be the governing body and the appointed members would be the voting party. Even if a public meeting was not deemed to be warranted, there could be an announcement in the Federal Register providing the recommended changes and asking for public comment. The recommended approach to this process is similar to the NUBC open meetings. The majority of coding professionals are anxiously waiting each issue of Coding Clinic to determine what items have changed and then to determine the impact on their operations. In many cases, this may result in re-doing educational offering or revising tools and resources used to facilitate the coding process. In many cases, there is also a need to quickly provide physician education on topics that are included. The FAH recognizes that CMS does not administer the process in which the official coding guidelines are developed, yet we respectfully request that since HIPAA deems this publication as the official guideline, CMS provide guidance to ensure that this publication is operationally applicable by allowing public comment on proposed guideline changes as well as ensuring that the publication is available in a timely manner. As an example, as of May 24, 2006, the First Quarter 2006 Coding Clinic has not yet been received. There is no accountability for the EAB to ensure that the publication of official guidelines on complex issues is addressed in a timely manner. The fact that updated coding guidelines over the next year are referenced in the Proposed Rule provides little comfort to the provider community that issues related to ongoing confusion will be addressed in a timely, operationally sound manner. It is our concern that the data improvement for the group of patients referenced in the proposed rule will be compromised and will not be available to meet the needs of CMS or the provider community. The FAH's members offer their assistance to CMS or others to achieve our common goal of providing timely and comprehensive coding guidelines to the HIM/coding professionals to ensure quality and data integrity in a complex regulatory environment.

Once again this year, the FAH requests reconsideration of changes to the current sepsis classification. Although CMS states that the current definition of severe sepsis is not specific enough at this time in terms of "clinical coherence or resource utilization" to warrant any changes, changes to the coding guidelines are already impacting the provider community. Specifically, coding guidelines have been revised based on clinical definitions, which in turn affected the DRG classification for sepsis. In many instances these DRGs are insufficient for the hospital resources provided.

The FAH recommends a recalibration of DRGs impacted by severe sepsis with respiratory failure when a patient is placed on mechanical ventilation. This proposal is based upon the resources consumed when a patient is maintained on mechanical ventilation for respiratory failure when the patient also has severe sepsis. According to the ICD-9-CM Code Book tabular and 4Q 2003 Coding Clinic pp 79-81, "For patients with severe sepsis, the code for the systemic infection (038.x) or trauma should be sequenced first, followed by either code 995.92, Systemic Inflammatory Response Syndrome due to infectious process with organ dysfunction, or code 995.94, Systemic inflammatory response syndrome due to noninfectious process with organ dysfunction. Codes for the specific organ dysfunction should also be assigned." As a result of this coding guideline, respiratory failure cannot be sequenced as the principal diagnosis because it is considered an organ dysfunction of the patient's sepsis. The resources consumed by a patient with severe sepsis who is placed on mechanical ventilation are significantly higher than a patient with severe sepsis who is not placed on mechanical ventilation. There currently is no DRG for sepsis that identifies the increased utilization of mechanical ventilation to appropriately represent the resources expended for these patients.

A potential approach to address this lack of recognition of resource utilization includes changing DRG 416 and/or DRG 475 based upon the impact of this coding advice. We recommend a DRG reclassification of severe sepsis with mechanical ventilation to DRG 475, with a revised title to read "Respiratory System Diagnosis or Severe Sepsis with Ventilator Support". Changing the DRG logic so that when a patient has respiratory failure as the principal or secondary diagnosis and is maintained on a mechanical ventilator support for longer than 96 hours would better capture the resources associated with caring for these patients. This recommendation is similar to the change CMS implemented in the FY 2006 final rule related to major cardiovascular conditions (MCVs) in which the MCVs could be present as either a principal or secondary diagnosis leading to greater resource consumption. Another option would be to create a new DRG for "Severe Sepsis with Mechanical Ventilation" with the appropriate reimbursement assigned to this DRG for resources consumed when a patient with severe sepsis is maintained on mechanical ventilation for organ dysfunction of respiratory failure.

7. <u>CC List</u>.

It does not appear CMS is using its routine criteria to add or delete a CC from the CC list. The codes for FY 2006 have only been utilized for the past 8 months. This does not allow enough data to be collected for a change in CC status. Furthermore, the National Kidney Foundation states that moderate and severe decreases in the GFR (Glomerular Filtration Rate) represent stage III and IV chronic kidney disease, respectively. It is with this information that we believe the revised codes for hypertensive kidney disease need further clarification and further data review prior to deleting stage III and IV from the CC list. Once a patient reaches stage III status he/she begins to exhibit the symptoms of a significant decline in kidney function (e.g., chronic anemia, hyperkalemia, toxicity, etc.).

The FAH opposes the new hypertensive kidney disease code assignments (403.XX and 404.XX). We believe it is premature to create these new codes based on data only after one year following implementation of the "new" hypertensive kidney disease codes. We do not feel there is enough data to support this change and are uncertain as to the clinical ramifications related to this change.

8. Changes to the ICD-9-CM Coding System.

As stated above, the FAH will express its members' concerns for coding changes to the appropriate parties as outlined in the Proposed Rule. We would also like to suggest a more cosmetic change to the tables appended to the Proposed Rule – we would recommend that the "revised" text in the tables in the Federal Register be bolded for ease of the end user.

II.E. DRG WEIGHTS

CMS proposes to change the DRG recalibration process methodology for FYE 2007 to move to a cost-based approach using a hospital-specific relative value ("HRSV") system. CMS solicits comments concerning this new methodology to recalibrate DRG weights and the process for a transition from the current system.

1. DRG Weights.

a. Errors in the Computation of HSRVs for the cost centers for each DRG in NPRM Part II.E, Table set forth at 71 Fed. Reg. at 24046-47.

The table that appears on page 24046-24047 of the Proposed Rule, pertaining to the 10 cost centers that CMS proposes to use in HRSV calculation appears to contain several inconsistencies. The FAH requests that CMS clarify precisely where specific items should be included. Generally, the FAH notes that the charge descriptions, derived by MedPAR, do not match the FORM CMS-2552-96 Cost Center description(s) for several cost centers. For example:

(1) MedPAR lists (18) Lithotripsy Charges where the cost reporting form lists Radioisotopes;

(2) MedPAR lists (6) Other Services where the cost reporting form lists Whole Blood and Packed Red Blood Cells;

(3) MedPAR lists (19) Cardiology Charges as including line 54 of the cost report, which is Electroencephalography;

(4) MedPAR lists (16) Blood Administration Charges where the cost reporting form lists ASC (Non-Distinct Part);

(5) MedPAR lists (24) Outpatient Services Charges where the cost reporting form lists Emergency;

(6) MedPAR lists (25) Emergency Room Charges where the cost reporting form lists Ambulance Services;

(7) MedPAR lists (26) Ambulance Charges where the cost reporting form has Renal Dialysis;

(8) MedPAR lists (29) ESRD Revenue Setting Charges where the cost reporting form lists Clinic;

(9) MedPAR lists (30) Clinic Visit Charges where the cost reporting form has Other Outpatient Services, Other Ancillary, Home Program Dialysis and Ambulance Services;

(10) Ambulance services appear to be included twice, once in (30) Clinic Visit Charges and once in (25) Emergency Room Charges;

(11) Lithotripsy is included in Cardiology Charges, which seems odd since it is not a cardiology service, at least not typically;

(12) Line 62 "Observation Beds" is not reflected separately in Table A. In situations where there is no distinct observation area, this cost would be included in the Routine Cost Center. In situations where there is a distinct observation area, the cost is not picked up since on the cost reporting form, the cost is recorded on Line 62.01. The FAH believes that Lines 62 and 62.01 should be included in Other Services and Charges and that Line 102 "Less Observation Beds" of the cost report should be included in the Routine Cost Center to avoid duplicating observation costs;

(13) Line 68 "Other Reimbursement" of the cost report is not listed in the Table at all. Other Ancillary on Line 59 of the cost report is reflected in (30) Clinic visit charges. In actual practice, on the cost report, this line is subscripted into various cost centers such an MRI, Cardiac Catheterization, Lithotripsy and others.

While these inconsistencies do not impact the conceptual basis of the use of HSRVcc's, the inconsistencies between the forms and formats call into question the accuracy and validity of the crosswalk to the cost report from MedPAR charge descriptions. This could become important, FAH believes, as the amounts become greatly magnified in the transition from a charge-based DRG system to a cost-based DRG system. The FAH requests, therefore, that CMS properly align these items prior to calculating DRGs under a cost-based system and furnish providers with appropriate revised forms as necessary with instructions regarding how to avoid duplications, omissions and/or other inaccuracies.

III. PROPOSED CHANGES TO THE HOSPITAL WAGE INDEX

B. CBSAs

As part of the transition to the new labor market areas that became effective for Medicare IPPS purposes with FY 2005, CMS allowed previously urban hospitals that became rural under the new definitions to maintain their assignment to the MSA where they were previously located for the 3-year period for FY 2005, FY 2006, and FY 2007. Specifically, during these three fiscal years, these hospitals were or will be assigned the wage index of the urban area to which they previously belonged, although for other purposes they will maintain their new status as rural hospitals. In the comments submitted last year by the FAH on the IPPS proposed rule for FY 2006, at page 16, the FAH stated that it had become aware of at least one situation where a new hospital was scheduled to open in a geographic area that is considered rural under the new labor market areas, but was urban under the previous definitions. We recommended that the policy be clarified to allow a new hospital in an area that is rural under the new classifications, but would have been urban under the old classifications, to also benefit from the three year transition period that has been granted to existing hospitals. Since newly constructed hospitals are some time in the planning, such hospitals were planned with the expectation of higher Medicare payments based on an urban wage index and should be equally protected from the reduction in the wage index that affects existing hospitals in the same geographic area. We cannot see any rational basis for distinguishing a newly constructed hospital from the other hospitals in its geographic area or in paying such a hospital with a lower wage index than its neighboring hospitals.

CMS failed to address this comment in the Final Rule for FY 2006. It continues to be an issue, as the FAH understands that at least one hospital in this situation has recently opened and, though as of yet not receiving any Medicare payments, has the current expectation that its rate may be determined based on the lower, rural wage index. The FAH reiterates its request for CMS to provide that a newly-constructed hospital in one of the urban-turned-rural areas be allowed to benefit from the transition payment during FY 2007 along with the other hospitals in such areas.

C. OCCUPATIONAL MIX ADJUSTMENT

The discussion in the Preamble regarding the occupational mix adjustment has been superseded by the Proposed Rule entitled "Hospital Inpatient Prospective Payment Systems Implementation of the Fiscal Year 2007 Occupational Mix Adjustment to the Wage Index," which was published in the Federal Register on May 17, 2006, 71 Fed. Reg. 28644. The FAH has submitted comments on this Proposed Rule in a separate letter and directs CMS's attention to those comments.

H. HOSPITAL REDESIGNATIONS AND RECLASSIFICATIONS

CMS has included several proposals to address the fact that Section 508 reclassifications are set to expire on March 31, 2007, half-way through the federal fiscal year. CMS has established procedural rules for hospitals that wish to apply for individual reclassification for the

second half of the fiscal year. CMS has also proposed that hospitals that are reclassified only for half of the fiscal year would receive two different wage indexes for the two halves of the year. Because this would impact the budget neutrality adjustment, CMS had to consider how to handle that impact. CMS has elected not to calculate two different adjustments, which would result in two separate IPPS standardized amounts for all hospitals; instead, CMS proposes to calculate one budget neutrality adjustment that reflects the average of the adjustments required for the first and second half fiscal year reclassifications.

The FAH has carefully reviewed the proposals in this section of the NPRM and believes that CMS's approach to these issues is very reasonable. Therefore, the FAH is fully supportive of the proposals regarding hospital re-designations and reclassifications.

IV.A. HOSPITAL QUALITY DATA

The FAH supports the voluntary submission and publication by CMS of information about hospitals' performance regarding patient care. The FAH is pleased that its member hospitals were in the vanguard of those facilities reporting such data on the CMS website in late 2003, which was even prior to the passage of the Medicare Modernization Act ("MMA") that established a financial incentive to submit such important quality measure information.

The FAH also understands and appreciates CMS' development of the infrastructure necessary to collect and report hospital quality data and to seek some balance in reconciling such collection and reporting obligation with Medicare payment policy. While the FAH continues to strongly support the overall concept of hospital quality measurement reporting and publication, and wishes to work closely with CMS in further developing this program, the FAH nevertheless believes that portions of the changes proposed by CMS in the FY 2007 IPPS Proposed Rule pose potentially serious concerns for the hospital industry. The FAH believes that these aspects of the current proposals can be significantly improved prior to final adoption and implementation.

1. Number and Type of Measures Required for Reporting to Obtain Full Update.

The Proposed Rule requires that hospitals report 21 quality measures beginning FY 07 in order to receive the full update. These 21 measures, covering three conditions—heart failure, heart attack and pneumonia—and one set of surgical infection prevention (SIP) measures, are currently endorsed by the Hospital Quality Alliance ("HQA") for reporting on Hospital Compare, the HHS web site that displays individual hospital performance on these measures. The Proposed Rule states that hospitals must submit these 21 measures for discharges from the first quarter of 2006 as one criterion for being eligible to receive the full Medicare update on October 1, 2006.

The FY 2007 IPPS Proposed Rule was published *after* the end of the first quarter of 2006. In order to be eligible to receive the full update, hospitals that did not collect data on all 21 measures for discharges from the first quarter of 2006 must now go back and commit necessary additional resources to collect data for those measures they are missing if they want to receive the full update. For example, published CMS data indicate that only 34 percent of

hospitals reported the SIP measures on Hospital Compare as of March 2006, the most recent update of the HHS web site. It will be a costly, inefficient and burdensome process for these hospitals and their vendors to go back and collect data on the SIP measures after their regular data collection efforts have concluded. FAH, therefore, strongly objects to this provision. It is basing critical eligibility criteria on a time period when hospitals had no knowledge what the FY 07 requirements could or would be.

2. Fiscal Year 2008 Measures.

CMS also proposes several additional measures that it is considering implementing for the subsequent fiscal year (FY 08). In particular, CMS indicates that it is considering adoption of three structural "Leapfrog Group" measures that hospitals may be required to report on in FY 08. The FAH strongly opposes any requirement that hospitals report on the three structural "Leapfrog Group" measures. The three measures involved are computerized physician order entry ("CPOE") implementation, referral of specific cases to "high-volume providers" as a matter of public policy, and the use of intensivists.

The three structural standards supported by The Leapfrog Group are best viewed as "aspirational best practices" (as The Leapfrog Group itself intended), as opposed to a national standard of care. Because the proposed standards represent "leaps" beyond normal practices, rural hospitals have not been asked to comply with the standards.

With respect to CPOE, implementation has been difficult due to the lack of standards, cost of implementation, and noncompliance by physicians. Additionally, published research has questioned the value of CPOE in terms of improving patient safety. Regarding the use of intensivists, for many if not most communities throughout the country, there are simply not enough intensivists to staff all hospitals. With regard to requiring referral of various patient conditions only to high-volume hospitals, the FAH believes that this is of mixed effectiveness. Volume does not always equate to quality. Information published by the National Quality Forum indicates that there are only a few procedures that have a strong positive correlation with good health outcomes.

As a result, FAH believes that it is unrealistic and unwise for CMS to adopt The Leapfrog Group's structural indicators as a mandatory reporting measure for inpatient hospitals in FY 08.

3. Efficiency Measures to be Pilot Tested

Section 5001 (a) (V) of Pub.L.109-171 states that beginning in FY 08, "...the Secretary shall add other measures that reflect consensus among affected parties, and to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities." Section 5001 (a) (VII) states that measures of hospital efficiency are one of the categories of measures that the Secretary shall report on the CMS web site. The Hospital Quality Alliance has begun a process to identify and test efficiency measures that will enable providers to reduce the number or intensity of medical services provided to a patient without withholding services that are likely to be beneficial to the patient's health and satisfaction. The intent of the HQA is to design and implement 2-year pilot test projects that would attempt to measure unnecessary and duplicative efforts; preventable complications; care coordination; and

services that add no improvement in patient outcomes. From this work, promising measures will be identified, evaluated, and sent to the National Quality Forum for endorsement as national standards so that they can be included for reporting by hospitals under the HQA.

4. Validation Issues.

a. General comments regarding validation process.

First, the FAH strongly recommends that CMS adopt a larger sample for validating hospital quality measure data. In particular, the FAH recommends that CMS use four quarters of data for validation, as CMS itself indicated it would plan to do for FY 07 in CMS' January 2006 letter to the Government Accountability Office ("GAO") (see Appendix IV: Comments from the Centers for Medicare and Medicaid Services, page 56, GAO-06-54). The FAH proposes, therefore, adding the fourth quarter of 2004 to the three quarters proposed, or some other suitable string of four consecutive quarters for purposes of reporting and compiling data. The FAH believes that the additional (one quarter's) five cases are needed to increase the sample size to a more credible and representative level and to create more stable results for individual hospitals.

Second, the FAH believes that appeals should also be permitted for validation tests scoring above the 80% pass level in any one quarter. At the present time, providers are not able to appeal an audit result above the 80% threshold on a per quarter basis. Since CMS intends to aggregate quarterly results, it is important that providers be able to appeal what they perceive and believe to be incorrect audit results, even if the provider has already passed the 80% threshold. If prior audit mistakes are not corrected, even though a provider may have scored 85% or 90% in that quarter, a subsequent lower quarter later in the year may tip the scales against an overall passing score, which could have been avoided if the provider was permitted to appeal what it believed to be an inaccurate or incorrect audit result in a quarter where the provider met the minimum 80% passing score. The FAH would like its members to have the ability to correct mistakes, even if the hospital would otherwise pass a quarter, so that the combined results for three or more quarters are not lowered unfairly.

Third, the FAH believes that the Proposed Rule is incomplete with respect to hospitals' attestations of data accuracy. The Proposed Rule states that CMS will provide additional information in the future. The FAH's concern is that because the requirement has the potential to become extremely burdensome, e.g., the FAH would not want a hospital statement to have to be notarized, and would not want the hospital statement to have been delivered prior to data submission, these types of issues should be ironed out and resolved prior to adoption. If the attestation of data accuracy can be performed as part of the data preview period, allowing the hospital Q-Net Exchange Administrator to review the data in the preview and electronically sign for its accuracy, the FAH believes that the system would function more smoothly and include the least degree of burden and highest degree of accuracy. Even if this cannot be accomplished temporally, the FAH believes that attestations by providers should be able to be delivered electronically, to ease any additional burden that may be imposed as a result of the attestation requirements.

Fourth, the Proposed Rule asks for guidance and comments on what the appeals process should be if an update is denied. The FAH agrees with CMS that something faster than the PRRB process is needed, given the backlog of PRRB cases and the length of time it takes for such a matter to proceed through the PRRB process. However, the FAH does not believe that shortening the time for filing an appeal or requiring an unrealistically short turn around time for an appeal would be the wisest choice. Ultimately, FAH members and indeed, all hospitals participating in an appeal, will want a fair yet reasonably timely process within which to present an appeal. Rushing the front end of the appeal process will not serve hospitals' ability to present accurate, well considered and suitably supported appeal positions. Rushing the back end of the decision making will probably result in occasional ill considered conclusions, incomplete consideration of all material factors and unfortunately, over time, inconsistent results.

The FAH believes that hospital chief executive officers should be able to submit their hospitals' appeals in writing, stating all reasons and facts that hospital believes it compiled with respect to the RHQDAPU eligibility criteria. The FAH believes that thereafter, CMS should establish a pre-PRRB review panel that does not involve any of the individuals who make the original determination. This panel will need adequate authority to make decisions in a timely fashion (for example within 60 days would appear to be more than appropriate). But if the preliminary panel's decision is against the hospital, the hospital should retain the right to have its appeal heard by the PRRB. This second level of appeal, naturally, will take more time, and will leave the hospital in a bit of uncertainty; however, since the hospital will already have received a formal response to its appeal at an earlier level, there would be more justification for delay at the second level, and the hospital will certainly have an idea as to what at least one decision maker thinks about the issue.

In addition, the FAH believes that data processing and communication errors that are under the control of CMS or the result of the actions of its contractors, should not be held against a hospital under any circumstances.

b. Data resubmission.

Current CMS policy does not permit resubmission of quality measure data after the submission deadline even if an error is identified. As a consequence, individual hospital performance information reported on the HHS Hospital Compare web site can be inaccurate. The FAH understands that the major objective of the Hospital Quality Alliance ("HQA") is to provide valid and reliable data so that consumers can make informed choices and decisions regarding their health care. If any part of the data are not correct, this objective cannot be met. Failure to allow providers to resubmit (corrected) data negatively affects not only the next release of data on Hospital Compare, but the next several releases, since data are reported for four rolling quarters.

The FAH requests that CMS consider a methodology that would allow resubmission of data in cases where incorrect data has been verified by the submitting provider, while still maintaining the integrity of the data validation process for payment purposes. The FAH does not believe that these two laudable goals are incompatible. CMS and its contractor should be able to establish two separate databases. The first would be frozen once the final submission deadline has passed to be used for CDAC validation. The second would allow for re-

submission after the deadline as it is inevitable that hospitals, QIOs, and vendors will find errors after the submission deadline. The need to correct the data on Hospital Compare will increase as the number and complexity of measures reported to HQA and the financial stakes for hospitals increase as well. This approach would create a stable universe from which to pull cases for validation, as well as serve the need to provide valid and reliable information to consumers. It would also further align JCAHO and CMS measures since JCAHO *requires* hospitals to re-submit data when a data or submission error is identified, regardless of when the error is identified.

c. Production of useful and actionable reports.

The FAH believes that CMS should create meaningful and useful reports for vendors after data submission that identify actionable steps hospitals are required to take to make sure they have successfully submitted the RHQDAPU measures. FAH requests that CMS modify the Failure and Success reports so that any data elements needed to populate or calculate measures reported for the APU would be identified as a critical error and result in the rejection of the record when the data element is missing or does not constitute a valid value. The FAH also recommends that CMS modify the Success report to allow downloading the entire report without the need to disaggregate it into several reports. (CMS currently places a forty MB limit on downloading reports.)

d. Access to Q-Net Exchange reports.

Hospitals that are owned by FAH member organizations generally rely on the administrative staff at their respective corporate headquarters to assist them in submitting quality data to JCAHO and CMS. Although these hospitals are 100% owned by the FAH member, the corporate administrative staff does not have access to all of the same reports that their organization's hospitals are permitted to receive or can receive on the Q-Net Exchange. In particular, owner hospital systems should be permitted to view "facility" reports, which provide both the denominator and the numerator for each measure. By having access to this report, corporate administrative staff can discern whether errors in data transmission have occurred and whether data should be resubmitted before the deadline. The FAH also recommends that CMS permit a hospital's vendor to have access to the facility reports. Again, the FAH believes that such access will facilitate and improve both accuracy and efficiency in preparing, submitting and correcting these reports.

e. Vendor relationships.

Vendors play an important role in RHQDAPU and HQA. However, the communication channel between CMS and the vendors is limited under current policy to a monthly conference call between the vendors and CMS/JCAHO staff. The conference call is generally conducted in a question and answer fashion, with vendors submitting written questions prior to the scheduled call. Many vendors consider the monthly call non-productive, unhelpful, and/or even confusing. The answers provided by CMS and JCAHO to the submitted questions, in light of the forum and process (not for lack of effort on the part of the vendors, JCAHO or CMS), are often incomplete and/or vague. Subsequent written answers are not distributed under current policy until several weeks after the call, which unavoidably results in somewhat dimmed

recollections of the issue. The technical quality of conference calls is also poor. It is not a moderated call and, as a result, background conversations and phones placed on hold often interfere with the ability of the participants to hear the answers being provided.

The FAH believes that the vendor information exchange process, including conference calls, is vitally important to the overall RHQDAPU and HQA processes. The FAH believes that CMS may not realize the degree to which hospitals rely upon their vendors. Within the context of JCAHO quality performance measurement, vendors are responsible for the successful participation of hospitals in providing data to JCAHO. Within this context, which was established prior to HQA, hospitals view the vendor role in very much the same way, i.e., vendors play a critical role in a hospital's successful participation in HQA and RHQDAPU. Hospital staff typically rely on their vendors for help in understanding communications from CMS, JCAHO and the QIOs.

The FAH encourages CMS to establish a formal advisory work group that would meet regularly with CMS and JCAHO to work on issues identified by Hospital Quality Alliance (HQA) stakeholders. This could be constructed as a subgroup of the HQA with relevant HQA principals identifying the vendors that should be represented on this advisory workgroup. We believe CMS would find this be a very beneficial endeavor. The FAH also recommends that CMS improve the technical quality of the monthly vendor calls by making them moderated calls.

5. Electronic Medical Records.

The FAH welcomes the opportunity to provide comments on electronic medical records (EMRs) and promoting effective use of health information technology (HIT).

In theory, EMRs could improve quality and safety, reduce costs and increase the accuracy of clinical data being exchanged among care providers, payers and other entities. EMRs could also help hospitals and other providers more efficiently report quality metrics to CMS and other payers. Ideally, the EMR should passively capture the underlying data set needed for quality reporting and be able to transmit such data without the need for subsequent editing/reformatting. Finally, EMRs could also improve practice through the use of clinical decision support tools.

Yet there remain a wide variety and number of legal, administrative, financial, regulatory, and technical barriers to realizing the above vision. At present, much of the required data for the Hospital Quality Alliance reporting process cannot always be reported at the time the clinical care is delivered but instead must be collected retrospectively. For example, much quality reporting is done using ICD-9-CM Diagnosis and Procedure Codes and/or Clinical Procedure Terminology (CPT) codes. In many IT systems used by large vendors, those data are only created during a coding process which occurs after a patient has been discharged. In some cases, the codes may in fact be changed at the point of final billing, which may occur while using the accounting, rather than the clinical care, software that hospitals use.

To cite yet another example, many quality measures are constructed from data that is derived from progress notes and other unstructured text fields. The workflow involved in

deriving quality data from such unstructured text is considerable. While advances in HIT are showing promise, robust, scalable solutions remain in the offing.

Moreover, these technologies do not appear to anticipate the probable addition of many new quality measures. The addition of fields not currently in EMR and EHR systems can have a cascading effect on costs, implementation, training and operational practices. Care needs to be taken in evaluating what data to collect to ensure that as little change as possible be made to the data model of core systems; each change drives modification to source systems, resulting in development, testing, quality assurance, and deployment costs, as well as delaying overall implementation. For example, querying a large number of patient records associated with a given condition may put substantial demand on system performance.

Organizations have tried to overcome this challenge by extracting EHR data from clinical data repositories (CDRs) and storing this data in external data warehouses that are specifically designed for analytical queries. These external data warehouses can automate quality measurement only if the source systems store all the required elements for reports. Some measures require data elements that are often difficult to collect electronically. For example, measuring aspirin on arrival for acute myocardial infarction (AMI) patients requires not only knowing if a patient has taken aspirin, but also the time the patient took the medication. An electronic medication administration record (eMAR) can document when aspirin is administered to a patient when they are in the emergency room, but if the patient takes aspirin en route to the hospital, this solution will not record the event. Hospitals that automate this documentation often implement solutions that prompt nurses and physicians to document this specific information in a structured fashion so that it can be warehoused for reporting.

Many EHR implementations have improved patient safety and reduced medical errors. Though many EHRs do not fully automate quality reporting, they do provide clinicians with the ability to view records remotely, thus easing the burden of accessing medical records for chart abstraction. Indeed, a 2005 Healthcare Financial Management Association study found that only 40 percent of hospitals surveyed that are using automated health information tools to support quality measurement reported a reduction in labor. The fact of the matter is that the current generation of EHRs do not have the capability to easily and consistently identify underlying data elements needed to create valid measures. As a result, vendor certification should not penalize hospitals that have already implemented EHRs. These initiatives must be carefully vetted so that current incentives are not diluted and the pace of EHR adoption consequently decreased.

In addition, if national quality reporting technologies are to be created around EHRs, there are lessons that can be gleaned from the hospital industry's early attempts to automate measurement. Some key considerations include the use of data and transmission standards as well as the importance of creating measurement systems which do not place unrealistic demand loads on EHR production systems.

Moreover, physicians who are unaccustomed to documenting in EHR templates may naturally resist adopting electronic structured documentation. Hospitals which rely upon physician admissions may therefore have a disincentive to install this functionality. Thus, appropriate incentives tied to EHR adoption which lead to fully automating quality reporting should be considered. To promote CPOE adoption, organizations such as the Leapfrog Group

have included this functionality in its hospital recognition and reward program. Similar incentives should be designed to reduce the financial risk of organizations making this transition. Such incentives will also create a market driver for vendors to develop and sell this functionality.

Besides technical and adoption issues, there remains the extremely difficult matter of financing these IT improvements. A 2005 AHA survey of hospitals and health systems showed that hospitals, on average, spent more than $700,000 in one year on the capital costs of health IT, representing 15 percent of all capital expenses. Hospitals spent even greater amounts, on average, $1.7 million, on health IT operating costs, representing 2 percent of all operating expenses. Survey respondents identified the upfront and ongoing costs of IT as the greatest barriers to further adoption.

The additional costs that hospitals may be expected to bear come at a time of decreasing reimbursement by public and private payors. Moreover, several studies have shown that the benefits of these hospital investments will largely be enjoyed by payors. Until standards exist and issues of equity and funding are addressed, adequate hospital investment in IT are unlikely.

a. Information technology measures.

The FAH believes that adoption now of a host of measures related to the hospital's use of IT is premature. Quite simply, the most advanced IT measures, which are believed, at first blush to improve quality of care, are not within the reach of many hospitals at this juncture, and many have not been proven empirically to make a significant difference in the quality of care. To impose such standards on a mandatory basis, with significant financial incentives and penalties, does not make sense from a quality (or cost) standpoint today.

b. XML.

The FAH opposes CMS' intent to develop measures specifications and a system or mechanism to accept data without converting it into XML. XML is a standard data transfer language. Moving away from XML would not only turn away from the trend of XML-driven service oriented architecture, but represents a direct assault on interoperability; the general trend of HIT architecture is to employ XML, which is used by the HL7 3.0 standard. Abandoning XML would destroy many hard years of work by the HIT industry to adopt a common standard.

c. Federal industry standards.

We are pleased that CMS is working with other federal agencies to develop health architecture data standards. The FAH supports the notion that hospital IT systems conform to federal health architecture data standards but only to the extent that they, in turn, adhere to industry standards. Clearly, if Federal and industry standards diverge, the administrative burden on hospitals will be incalculable.

d. Promoting the use of Health Information Technology.

The FAH does not believe that CMS has the statutory authority to encourage the adoption and use of HIT without new legislation. In general, the FAH believes that hospitals

should base their investment in HIT on their respective specific business models as they do with any other input, such as labor or plant. The FAH also believes that HIT should not be an explicit factor in any value-based purchasing program. HIT is but one of many inputs hospitals use to improve quality, including training. Well-designed value-based purchasing programs should reward hospitals and other providers on the basis of outcomes rather than on the use of certain inputs.

While FAH supports the notion that hospitals should use HIT that will be certified by the Secretary and the Certification Commission for Health Information Technology (CCHIT), it does not believe that using such technology should be part of a Condition of Participation. Again, the underlying issues of providing quality care and delivering value should not be dependent on particular inputs but rather the end result of the larger hospital system. The extent to which a given hospital provides quality of care should be determined by accreditors and quality metrics that are reported to CMS.

IV.B. VALUE BASED PURCHASING

In its March 2005 report to Congress, the Medicare Payment Advisory Commission ("MedPAC"), presented a series of recommendations regarding "Pay for Performance" stating that Medicare policy should explicitly link hospital payment and quality performance. The report indicated that Medicare, the largest purchaser of health care in the United States, pays all hospitals at the same rate regardless of the quality of care each provides. In this manner, MedPAC contended, current payment policy contains virtually no incentive to invest in or improve quality of performance. For the first time in any significant manner, CMS, in this Proposed Rule, is now recommending that some type of "value based purchasing" or "pay for performance" based system be introduced, as early as fiscal year 2009 for purposes of the Medicare program. CMS has requested comments on a variety of issues related to this proposal, and the FAH welcomes the opportunity to offer its views.

In designing a payment system that better links performance to payment, FAH's goal is to balance two critically important factors. Higher quality hospitals should, indeed, be recognized; however, no payment system should impede or create barriers to appropriate high quality care for all patients. Payment systems must ensure that evolving and improved technologies continue to be available for all patients, and that no payment system linking quality to payment unfairly punishes hospitals that are seeking to improve, thereby crippling such provider's ability to deliver good quality care to the population served by that facility.

1. Measure Development.

- *Selecting measures for payment for performance.*

The FAH generally agrees with the measure criteria in MedPAC's 2005 report to Congress regarding pay for performance and value based purchasing. However, the FAH would more clearly emphasize that hospitals must be in control of the measurement process and be able to improve upon it. Hospitals cannot be held accountable (with respect to monetary impacts)

based on measures outside of their control. Any system linking performance to payment must also recognize that hospitals and physicians broadly share responsibility in delivering high quality and safe care. Thus, hospital and physician quality based performance incentives or penalties should be closely aligned and must be within the control of hospitals and participating physicians to be effective.

- *Measures for reporting or payment.*

The FAH supports using the multi-stakeholder HQA to identify the next set of measures for reporting, and eventually, for payment. The FAH believes that this type of process, one in which stakeholders are intimately involved, is the most effective way to promote change as quickly as possible with the greatest acceptance of that change. As the Proposed Rule states, "The efforts of CMS and its stakeholder partners to develop standardized performance measures increase the likelihood that the measures will be valid, reliable, and widely accepted as viable indicators of performance."

FAH, as well as the HQA, supports the addition of the surgical care improvement project ("SCIP") measures. The FAH believes that these measures are consistent with the policies espoused by MedPAC in the latter's March 2005 report to Congress concerning value based purchasing measures. The FAH, however, does not support the proposed measures related to a hospital's use of information technology ("IT"), implementation of data standards and the proposed standards relating to preventable readmissions. These standards do not meet the MedPAC criteria. MedPAC has among other things recommended: (i) that any measures ultimately adopted should be evidence based, (ii) that collecting and analyzing the data should not be unduly burdensome for the provider or CMS, (iii) risk adjustment should be sufficient to deter providers from avoiding patients who might lower performance scores, (iv) measures should be adopted whereby most providers should be able to improve on such measures, (v) measures should apply to a broad range of care and providers, (vi) measures should capture aspects of care that are under the control of the providers being measured, and (vii) the areas of care being measured should be those needing improvement.

- *Measures should be practical and manageable for hospitals to collect.*

As hospitals reach higher levels of performance, old measures should be retired to maintain a manageable and focused program. A life cycle of measures should be initiated and continually updated, so that hospitals may proceed through a spectrum of improvement with reasonable but perceptible rewards.

2. <u>Confidentiality</u>.

Given that value based purchasing and payment for performance are evolving concepts, there is currently uncertainty as to how a final system may look. Under any possible final scenario, one hospital priority is to ensure that hospital-specific, patient-specific data that is reported for purposes of generating a payment decision is treated by the government and its contractors as confidential and generally protected from public disclosure. In particular, such data should be protected from disclosure to third parties for purposes of discovery in private lawsuits or for other purposes unrelated to Medicare payment or quality reporting.

The federal government and its contractors are governed by multiple confidentiality laws and regulations with regard to those entities which provide services under federal health care programs, and many of those protections would seem to apply to a value-based purchasing program. However, in developing such a system, CMS should focus on ensuring that the raw data received from providers that is used to make payment decisions is protected from unintended disclosures to third parties that may use this valuable information for unrelated purposes.

3. **Data Infrastructure.**

- *Carefully consider HQA recommendations.*

The HQA is engaged in a study to build consensus among its members, including CMS, on a framework for collecting, storing and using hospital quality data for all stakeholders. The FAH believes that the HQA constitutes a representative sample of the various regulators, vendors and provider stakeholders in the health care industry and that prior to issuing any final determination in this or a subsequent rule, CMS should carefully consider the recommendations of the HQA with respect to collection, storage and use of hospital quality data.

Any common national platform of quality performance measures that is adopted should be made available to all users – public and private payors, regulatory and accrediting entities, and consumer organizations. Standardizing quality measurement at the national level provides the greatest opportunity for improvement and public accountability by focusing national attention on the same priority areas and permitting comparisons among hospitals on the same performance measures. Such a system will also likely reduce conflicting or competing measurement information, and help streamline hospital data collection and reporting, greatly minimizing the inefficient and costly process of providing different information to different organizations, and regulatory bodies.

A preliminary set of recommendations is expected to be discussed at a June 20, 2006 HQA meeting. The FAH hopes that the HQA will reach consensus on a detailed plan by the end of this year. Until that plan is developed, however, FAH, as well as HQA, are not in a position to recommend whether or how CMS should build a hospital data infrastructure. The FAH, for its part, urges CMS to work closely with HQA in developing an appropriate data infrastructure.

4. **Reducing Lag Time Between CMS Receipt of Data and CMS Ability to Provide Feedback.**

CMS has requested comments on how to reduce the lag time between its receipt of data and its ability to provide feedback to hospitals. After carefully reviewing CMS' proposed policies, the FAH concludes that none of the options presented are acceptable. If CMS' objective is to reduce the lag time in order to provide feedback to hospitals on their performance, the FAH believes that it currently does not take the nine full months that the Proposed Rule states it does. Vendors can, and do, often provide feedback to hospitals on their performance at the times they collect and submit the quarterly data, about four to five months after the discharge

occurs. Although the data have not gone through full validation at that point, the feedback is generally reliable and it is of great assistance to the hospitals receiving it.

The FAH does not believe that monthly submissions make sense. The amount of administrative time involved would be extremely burdensome to hospitals, and frankly, would leave fewer resources to actually work on improving quality. While some hospitals submit quality data on a monthly basis to JCAHO, this is not necessarily the norm, and many hospitals, most likely the ones that could least afford it, would be forced to spend inordinate amounts of time submitting data on almost a constant basis. Shortening the data submission period is not a workable option. Hospitals need time to prepare the information for submission and cannot be placed under even more demanding deadlines in this process. The number of agencies to which hospitals report data is growing and hospitals are significantly burdened already.

Elimination of the validation appeals process would also hurt, rather than help, hospitals in their pursuit of higher quality of care. Hospitals believe that the validation appeals process is important, and a vital piece of the process. Given the increasing magnitude of Medicare dollars at stake, hospitals must have every opportunity to pursue legitimate appeals.

5. Incentive Methodology.

The FAH believes that linking payment to quality of performance is a relatively nascent concept with little real world experience on a proven platform. The FAH believes that initial efforts to implement value based purchasing should be incremental, recognizing the limits of what we as an industry collectively understand about the underpinnings and design of such a system. The design of any such system must also be flexible enough to change relatively quickly without disrupting hospital, vendor or CMS operations. The program should also be adjustable, as needed, based on periodic evaluation, to ensure the design is meeting the overall goal of incentivizing top quality performance.

An equitable share of incentives should be directed toward demonstrating improvement. Hospitals with the lowest quality scores should not be punished under the system, at least at its inception, if such hospitals can demonstrate improvement over a reasonable period of time. In addition, the FAH believes that the incentive (as well as the penalty) structure should be transparent, administratively simple, and predictable for all hospitals. Also, there should be a direct link between the incentive (and penalty) payments and the clinical performance that is being measured.

Financial incentives (and penalties) should also be modest, yet adequate to produce the desired changes. Incentives and penalties should exist over a fairly broad spectrum of performance, so that those facilities at the lower end of performance can improve modestly and be rewarded, those in the middle can move higher and be rewarded and those starting out at the upper end may also have incentives in their future. By the same token, penalty payments or disincentives should also be gradual and should not produce "cliff" effects in terms of either incentive or penalty payments. Sharp divisions between quality categories, leading to overly harsh penalties or unrealistic incentives could produce such "cliff" effects and encourage gaming and other undesirable behavior.

The FAH believes that all Medicare funds designated for rewarding quality performance should be fully allocated back to hospitals. A program designed to reward hospitals for improving quality should not become a cost cutting mechanism. Rather, it should be a modest redistribution to higher quality performers from providers that are not making the effort and/or achieving the results of quality improvement.

The FAH also recommends that any value based purchasing system's implementation be synchronized with other federally mandated system changes that affect hospital payment (e.g., HIPAA, coding changes, etc.).

Regarding the use of composite scores for reporting or payment, the FAH believes such measures should be subject to the consensus development process of the National Quality Forum and have the support of the HQA.

6. Public Reporting.

FAH members have been leaders in hospital public reporting since the HQA voluntary reporting effort was launched in December 2002. No additional stimulation to publicly report is necessary. FAH members recognize that public accountability of their quality performance is necessary and important and they are committed to remaining active participants.

7. Hospital Acquired Infections DRG Adjustment.

Section 5001 (c) of Pub. L. 109-171 requires the Secretary to implement, beginning October 1, 2008, a change in DRG payments that would reimburse hospitals for select DRGs with complications or comorbidities (CC) at the DRG rate without complications or comorbidities. By October 1, 2007, the Secretary is required to identify at least two conditions that meet the following criteria:

- high cost or high volume or both
- results in a higher payment DRG when a secondary diagnosis is present
- the higher payment DRG could have been prevented through the application of evidence-based guidelines.

To implement this provision, Pub. L. 109-171 requires hospitals to submit the secondary diagnoses that are present on admission when reporting payment information for discharges on or after October 1, 2007.

a. Secondary diagnosis present at admission is not readily available.

The National Uniform Billing Committee approved the UB-04 paper claim and data set as the replacement to the existing UB-92 paper form in February 2005. The UB-04 supports the ability to report whether a particular diagnosis code was present at the time of admission or whether it occurred subsequent to admission. While there is currently a data limitation with the current version of the electronic institutional claim, the ANSI X12N 837, the upcoming 5010 version of the electronic standard is being designed to support the indicator. As

hospitals are required to use the 5010 under HIPAA, virtually all hospitals are scheduled to begin including this data field tentatively in the 4th quarter of 2009, fully two years *after* the required reporting date contained in Pub. L. 109-171. Following this schedule, the earliest that CMS could implement a change in DRG payments would be October 1, 2010 (FY 2011).

b. National guidelines needed.

Currently there is no standard set of definitions or guidelines to follow when coding the present on admission indicator on the Medicare billing form. The cooperating parties for the publication Coding Clinic for ICD-9-CM have been developing such guidelines which are expected to become available October 1, 2006. Until such guidelines become available and are field tested, we cannot evaluate the reliability or validity of the information reported on secondary diagnosis. This analysis is necessary before the data can be used for payment purposes addressing hospital-acquired infections.

c. Major education and system changes necessary.

To help ensure that the data collected on secondary diagnosis upon admission is accurate, it will be important for those coding the information to be trained to reliably interpret the national guidelines. Hospitals will also need to make necessary changes to their coding and billing systems to ensure appropriate assignment and data capture. Again, the industry is unsure at this time how this indicator can be incorporated into operations and then provided to CMS on electronic claims by 10/1/07. CMS must allow adequate time for hospitals to conduct training and programming changes before implementing Section 5001 (c).

8. Financial Impact Is Unpredictable Given Simultaneous and Significant DRG Reform.

The Proposed Rule also suggests significantly changing the current DRG structure, by implementing consolidated severity adjusted ("CSA") DRGs no later than FY 08. CMS needs to explicitly articulate how the payment provisions of Section 5001 (c) will be implemented under CSA DRGs. If the current DRG structure continues, CMS needs to clarify under what conditions hospitals will receive the lower DRG payment when more than one complication or comorbidity is recorded on the billing form.

IV.C. SOLE COMMUNITY HOSPITALS ("SCHs") AND MEDICARE DEPENDENT HOSPITAL ("MDHs").

3. SCH/MDH Changes In Qualification Status.

The sole community hospital (SCH) designation was established by Congress to identify and assist hospitals that are geographically isolated and financially vulnerable. The FAH agrees that hospitals that do not maintain the qualification criteria should not retain SCH designation. However, the FAH contends that the proposed reporting requirements and penalties should be revised to be consistent with the intended purpose of the SCH program. We agree that a hospital which qualifies by being located more than 35 miles from another "like hospital" is likely to be

aware when a new facility opens within a 35-mile radius. However, we believe that hospitals will encounter great difficulty in monitoring ongoing compliance with other SCH qualification criteria.

Certain other qualification criteria are more complicated and more difficult for hospitals to monitor. For example, to qualify under 42 C.F.R. § 412.92(a)(l)(i), hospitals would be required to access data on inpatient admissions at other area hospitals, and would likely have to obtain this information from state hospital associations or their fiscal intermediaries. This is burdensome at best, and may also not be an accurate up to date source of information in some cases. Likewise, a hospital that qualifies for SCH status because a nearby provider is not a "like provider" is likely to be unable to ascertain if and when the nearby hospital exceeds the eight percent (8%) threshold which would then qualify that provider as a "like hospital." Again, this creates a significant burden on SCH hospitals, which such hospitals may not be able to satisfy.

Also, hospitals should not be expected to and cannot monitor and know when and for how long there may have been prolonged severe weather conditions that closed area roads, and thus to know whether they continue to qualify under §412.92(a)(l)(iii) or (a)(2). Similarly, it is unreasonable to expect hospitals to monitor and know whether traffic patterns or posted speed limits in a particular region have changed such that they no longer qualify under §412.92(a)(3). CMS should be required to keep track of these items and notify intermediaries and/or providers.

The FAH believes, therefore, that CMS should continue to bear the responsibility for determining and verifying SCH status with its fiscal intermediaries, at least in every circumstance except where a hospital qualifies by being more than 35 miles from another "like hospital."

The FAH also has concerns about the proposed timetable for canceling SCH status when a hospital self-reports. Losing SCH status could result in a severe financial impact to a hospital. Thirty days does not provide a hospital with adequate time to plan for such a payment reduction. Instead of a 30-day timetable, we recommend revoking SCH status for hospitals that self-report as of the later of six (6) months after the change/report or the start of the hospital's next cost reporting period.

The FAH also is concerned about the proposed establishment of a retroactive penalty in cases where a hospital fails to immediately notify CMS that it no longer meets the SCH qualification criteria. Based on the difficulties described above in accessing qualification criteria, the FAH believes that these penalties should apply only in circumstances where a hospital loses SCH status because a "like provider" has opened within 35 miles. To apply such retroactive penalties in other cases would be overtly punitive where the hospital has done what it reasonably can do to assess its status and has not acted otherwise inappropriately in any manner.

As a protective measure to SCHs, the FAH also encourages CMS to specify that "specialty hospitals" (such as those specializing in cardiac surgery/care or orthopedic surgery) be excluded from potential designation as a "like hospital." A specialty hospital could presumably meet or exceed the 8 percent inpatient days threshold, even though it could be an entirely different type of hospital than the neighboring SCH, and serve an entirely different community need.

Pursuant to the Proposed Rule, new reporting requirements also are being imposed on MDHs. Among these new requirements is a "self-reporting" requirement that an MDH will be responsible for reporting any material change in status or risk sudden loss of MDH status and/or penalties.

One of the items that MDHs are being asked to monitor and report falls under 42 C.F.R. § 412.108(a)(1)(iii)(C), and requires MDHs to report if they no longer can demonstrate that at least sixty percent (60%) of the hospital's inpatient days or discharges were attributable to individuals receiving Medicare Part A benefits during "at least two of the last three most recent audited cost reporting periods for which the Secretary has a settled cost report."

Clearly, with regard to this item, the fiscal intermediary, and thus, the Medicare program, will know about the provider's inability to meet this qualification criterion long before the provider. The determination is based on audited, settled cost reports; the provider could only know what it filed, not what ultimately was allowed by the intermediary after reviewing Medicare program logs.

The FAH believes that on this one item, a strict reporting requirement creates an unfair burden for MDHs to monitor events that are not within their control. The FAH, therefore, requests CMS to omit entirely from any final rule all self-reporting requirement(s) as they apply to circumstances arising under 42 C.F.R. § 412.108(a)(1)(iii)(C).

IV.G. GEOGRAPHIC RECLASSIFICATION

4. Urban Group Hospital Reclassifications.

The FAH applauds CMS's decision to modify its regulations so that urban counties within a Core-Based Statistical Area ("CBSA") will be deemed to have met the proximity requirement for urban group reclassifications. With this regulatory change, urban county group reclassifications between Metropolitan Divisions in a CBSA will be allowed in addition to urban county reclassifications within a Combined Statistical Area ("CSA").

Despite CMS's statements that it sought to allow urban group reclassifications and to leave unchanged their right to reclassify after the revisions to geographic areas that had been adopted in FY 2004, CMS's limitation of such reclassifications to those counties within CSAs had effectively excluded one group of hospitals, those located in Palm Beach County, Florida, from being able to reclassify to the Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Division of the Miami CBSA. Last year, in its comments to the IPPS proposed rule for FY 2006, the FAH, among others, urged CMS to make the change that it has made this year. The FAH is very pleased that CMS carefully considered the comments that were made and has agreed to make this change. In making this change, CMS commented that the "proximity standard for group reclassifications is intended to allow all of a county's hospitals to reclassify to an adjacent area where there is sufficient economic integration that there can be an expectation that both areas are competing in a similar labor market area." CMS stated that it agreed that there was

sufficient economic integration within a CBSA, so that urban county reclassifications within a CBSA, as well as a CSA, should be permitted. (71 Fed. Reg. at 24109-110).

Based on the above-stated policy considerations, there is no reason why the hospitals of Palm Beach County should not have been eligible to reclassify for FY 2007. However, because CMS is only now making the necessary regulatory change, these hospitals have lost their chance to reclassify. The hospitals of Palm Beach County did file a timely group request for reclassification for FY 2006, but it was denied. Because the deadline for submitting a group reclassification application for FY 2007 was September 1, 2005, it is now too late for the hospitals to benefit from CMS's recognition of the appropriateness of modifying the pertinent regulation.

Accordingly, the FAH requests that CMS exercise its broad authority and discretion to allow for a one-time reclassification for Palm Beach County hospitals to the Fort Lauderdale-Pompano Beach-Deerfield Beach, FL Division of the Miami CBSA for FY 2007. CMS has exercised such authority before. For example, CMS allowed certain hospitals whose reclassification applications had been denied to benefit from the wage index which they would have been assigned if those requests had been granted, because it recognized that certain criteria that had been in effect were no longer appropriate. In making this exception, CMS stated:

> In light of the fact that the standardized amount criteria are no longer appropriate, we believe it would be appropriate to make an adjustment to the hospital's wage index by assigning, to hospitals that were unable to reclassify in applications for both FY 2004 and FY 2005, the wage index for the MSA requested in the FY 2004 and FY 2005 group application. Section 1886(d)(5)(I)(i) of the Act provides the Secretary with broad authority to make adjustments and exceptions under the IPPS. Specifically, the section provides that the ``Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.'' Under this unique circumstance, in the May 18, 2004 proposed rule, we proposed to exercise the broad authority under section 1886(d)(5)(I)(i) of the Act, to make an exception to the assignment of wage index value for certain hospitals that failed to reclassify as a group under Sec. 412.234 for FY 2004 and FY 2005.

69 Fed. Reg. at 49104. The FAH requests that CMS exercise its authority in the similar situation presented here.

5. Effect of Change of Ownership on Urban County Group Reclassifications (§§ 412.230, 412.234, and 489.18).

Pursuant to 42 C.F.R. § 412.234(a)(1), for urban hospitals seeking redesignation as a group to another urban area, all hospitals in the county must apply. Redesignations granted pursuant to this provision last for three years, in accordance with 42 C.F.R. § 412.274(b)(2). The FAH understands that it is CMS's position, though not specified in the applicable regulations,

that a new provider in a county that has applied for and obtained redesignation, cannot benefit from the group reclassification, but will receive the wage index of the geographic area where that hospital is located. Further, we understand that it is CMS's position that a second group application, which could include the new hospital, cannot be submitted until the three years has expired from the MGCRB's original grant of redesignation. We understand that this unpublished policy applies both to newly-constructed hospitals, as well as hospitals with new ownership that have applied for a new Medicare provider number, rather than assume the provider number of the seller.

In its comments on the IPPS proposed rule for FY 2006, at page 40, the FAH stated its opinion that such a policy is unfair to new hospitals, putting them at a competitive disadvantage with the other hospitals in the county. Since such reclassifications last for three years, a new hospital will be forced to accept a wage index lower than all other hospitals in its area for up to the three year period. This policy is inconsistent with the policy pertaining to the situation where all hospitals in a State seek a statewide wage index redesignation. In that situation, pursuant to § 412.235(b)(2), any new prospective payment system hospital that opens in the State during the effective period of an approved statewide wage index reclassification will be designated to receive the statewide wage index for the duration of that period. The FAH urged CMS to reconsider its policy preventing new hospitals from joining existing urban county group reclassifications, or, at a minimum, to explain the reasons for its policy and include it in the regulations.

CMS failed to address this comment in the Final Rule for FY 2006. However, in the Proposed Rule for FY 2007, at p. 24110, CMS states that a new hospital, though prevented from individually reclassifying until it accumulates at least one year of wage data, may join a group reclassification with all other hospitals in its county. In stating this policy, CMS indicated its belief that allowing group applications would be unfair to new hospitals because it would put them at a competitive disadvantage with other hospitals in the county by forcing the hospital to accept a lower wage index than all other hospitals in the county with which it competes for labor.

While CMS thus recognized that new hospitals should be allowed to join urban county group reclassifications, under existing policy, its pronouncement will only be effective for new hospitals who begin operations at the same time that the urban county is submitting its application for a group reclassification. It does not appear that new hospitals would be able to join an urban county group reclassification that is already in effect, until such time as the 3 year period of the reclassification expired. The FAH requests that CMS modify its regulations to allow for new hospitals to immediately benefit from urban county group reclassifications or otherwise explain why existing regulations would allow for that to occur.

6. Requested Reclassification for Hospitals Located in a Single Hospital MSA Surrounded by Rural Counties.

CMS is seeking comments on the request by one commenter that CMS should change urban county group reclassification regulations so that a hospital in a single hospital MSA surrounded by rural counties would be able to reclassify to the closest urban area that is part of a CSA located in the same State as the hospital. There are three particular aspects of this request on which CMS has sought comment:

1. Should a hospital in a single hospital MSA be permitted to reclassify, when in fact its wage index directly reflects the wages that it pays?

2. Should some increased wage index be allowed for a hospital that is located in an urban county entirely surrounded by rural counties and within a modest distance of a number of hospitals that have received one form or another of special payment status relating to their rural locations?

3. Should a hospital be allowed to reclassify to a labor market area that is further away than other, closer urban market areas?

The FAH believes that making an exception for the hospital addressed here would be an unnecessary expansion of the geographic reclassification provisions. In particular, the FAH notes that it believes that it would be inappropriate to allow for reclassification to another area for a hospital that is paid based solely on its own wages and agrees with CMS that the wage index is operating with substantial precision in this case. The FAH also is not comfortable with the idea that an urban hospital could be allowed to reclassify to a labor market area that is farther away than closer urban market areas.

The FAH believes that reclassifications are justified when there is support that a hospital is an integral part of the labor market to which reclassification is sought. Where a hospital is the sole hospital in the labor market MSA or where a hospital seeks to reclassify to a MSA further than the nearest MSA that is outside the existing mileage criteria, there is little likelihood that such hospital is an integral part of those labor markets. In this situation, the FAH does not think that the hospital is competing for staffing with these distance areas.

In regard to the second question posed above, the FAH is not unsympathetic to the situation described of a hospital that is surrounded by rural hospitals that have all received special payment status. The FAH might support some accommodation that was particularized to this situation, but it believes that the suggested solution, which would allow the hospital to reclassify to a distant area, is not appropriate. However, we believe that CMS should solicit comments on such a proposal prior to implementation.

IV.H. GRADUATE MEDICAL EDUCATION

1. Background.

FAH notes that intermediaries (and certain software programs) apparently continue to use the initial residency periods ("IRP") set forth in the August 30, 1996 Federal Register. 61 Fed. Reg. 46,166, 46,210 (Aug. 30, 1996). For all podiatry residency programs, CMS set forth an IRP of two years in the August 30, 1996 Federal Register. Id. However, the Council on Podiatric Medical Education ("CPME") has recognized since at least 2003 that there are two types of podiatry programs: a two year Podiatric Medicine & Surgery ("PM&S")-24 program and a three year PM&S-36 program. See www.cpme.org. Significantly, according to 42 C.F.R. Section 413.79(a)(7), the IRP for any podiatry program is the minimum number of years of formal training established by the accrediting agency, i.e., CPME. Thus, the IRP for PM&S-36 should

be three years and not the two years listed in the August 30, 1996 Federal Register. With respect to setting the IRP, FAH requests that CMS direct all intermediaries to use the most up-to-date information on the length of the relevant training programs as set forth by the relevant accrediting agencies.

2. **Determination of Weighted Average Per Resident Amounts for Merged Teaching Hospitals.**

a. FAH generally supports the proposal to compute a merged average per resident amount ("APRA") using data from the most recently settled cost reports of hospitals that experience a merger. However, FAH believes that both the three-step methodology set forth on page 24112 (middle and right columns, especially the "example" provided in step 2) and the specific example provided on pages 24112-24113 should be clarified in several respects. First, FAH suggests that CMS indicate the date of the merger. Second, FAH suggests that CMS clearly indicate the pre-merger fiscal year ends of the hospitals in the merger and also indicate specifically the fiscal year end of the latest settled cost report for each such hospital. Finally, FAH requests that CMS expressly note the effective date of the updated/merged APRA for the surviving hospital. See infra section IV.H.2.b.

b. Additionally, FAH believes that mergers can often involve certain complicating factors that are not addressed in the Proposed Rule (or in the example). For instance, CMS should indicate its view of how specifically to address a merger that occurs in the middle of the surviving teaching hospital's fiscal year. Would that surviving teaching hospital have two APRAs in the year of the merger (one pre-merger and one post-merger)? Or, would the merged APRA only become effective with the start of the fiscal year subsequent to the merger?

c. FAH requests that this latest CMS policy on the treatment of merged hospitals' APRAs be expressly included as a provision in the text of 42 C.F.R. Section 413.77. This latest version of the merged hospital policy sets forth detailed instructions and guidelines and crystallizes longstanding policy that has not previously been set forth in the regulations (or anywhere except the Federal Register preambles). FAH believes it would be more appropriate to set forth the merged APRA (and merged full time equivalent cap) policy in the text of the regulation.

d. In the proposed method of calculating the weighted APRA for merged teaching hospitals, the intern and resident full time equivalents ("FTEs") for primary and non-primary programs of the teaching hospitals are suggested to be the sum of Lines 3.07, 3.08 and 3.11 of the hospital's most recently settled Medicare cost report, CMS 2552-96, Worksheet E-3, Part IV) (Step 1). 71 Fed. Reg. at 24112 (middle column). However, the FTE counts reported on these lines are for the one current year only. For merged teaching hospitals, FAH believes that a more accurate and appropriate methodology would use the three year rolling average FTE count in the most recent settled cost report. In the merger of two existing teaching hospitals, the proposed use of a one year FTE count methodology is not appropriate (or most accurate) because existing teaching hospitals are reimbursed for direct GME based on the 3 year rolling average of weighted FTEs for primary and non-primary programs. The current year's weighted FTE count represents only one of the 3 years required in the rolling average calculation and used for

ultimate GME reimbursement. Thus, FAH proposes that CMS use the FTE counts on lines 3.16 3.22 for purposes of developing the weighted, merged APRA. These lines set forth the actual FTE counts (after rolling average and exceptions to the rolling average) that are used for reimbursing GME to the merged hospitals on their latest settled cost reports.

e. In a merger of an existing teaching hospital and a new teaching hospital (still exempt from the rolling average), the new teaching hospital will have a zero FTE count reported on Lines 3.07 and 3.08 because the resident counts are required to be reported on Lines 3.16 and 3.22. In addition to the reasons set forth in paragraph D above, FAH believes that in this situation using Lines 3.16 and 3.22 is necessary to accurately and fairly capture all of the resident FTE counts for all parties to the merger and will result in a more representative APRA for the merged hospitals.

f. FAH believes that the post-merger weighted APRA for merged hospitals should be split into two separate APRAs (primary and nonprimary) if any of the merged hospitals has separate pre-merger primary and nonprimary APRAs. FTE counts for primary programs are still required to be reported separately from non-primary programs even if a hospital does not have different primary and nonprimary APRAs. FAH believes that unless and until the separate reporting of FTE counts is revised into a single FTE count, it is not particularly administratively convenient to apply a single APRA for merged hospitals. Further, existing hospitals with two APRAs are allowed to continue using two APRAs whereas merged hospitals with two APRAs are required to use a single APRA. This might result in unequal treatment and may end up being inaccurate especially if the surviving hospital's mix of primary and nonprimary residency programs changes significantly (compared to the pre-merger mix for any or all of the hospitals involved in the merger). Essentially, the use of two APRAs post-merger results in more accurate reimbursement than a single APRA. FAH requests CMS to reevaluate the proposed single APRA for merged hospitals.

3. Resident Time Spent in Nonpatient Care Activities as Part of Approved Residency Programs.

FAH urges CMS to modify or rescind its "clarification" in the Proposed Rule that excludes medical resident time spent in didactic activities in the calculation of GME and indirect medical education ("IME") payments. The Proposed Rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the FTE counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This previously unpublished position is in stark contrast to CMS's position as recently as 1999, at which time the Director of the Division of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. FAH concurs with the CMS's 1999 position. The activities cited in the 1999 letter and cited again in the "clarification"

are an integral component of the patient care activities engaged in by residents during their residency programs.

There are very few residency experiences that are not related to patient care activities. The learning model used in graduate medical education is the delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

To exclude the resident time spent in case conferences, lectures, journal clubs, and other didactic activities for IME reimbursement would have a significant financial impact upon many teaching hospitals. FAH members have invested a significant amount of financial resources in developing conference rooms, classrooms, computers, and audiovisual equipment in order to provide an excellent teaching environment for resident physicians. This is frequently the setting in which residents learn how to use the electronic medical record, the digital imaging systems, the maternal-fetal monitoring systems and how to better manage patient care through the use of new technology.

FAH teaching hospitals are also financially responsible for expenses associated with sending resident physicians to seminars and other training sessions outside of the teaching hospital setting. The typical per resident amount does not cover the cost of the resident's salary and benefits. Further, teaching hospitals are also required to compensate the nonhospital sites for resident teaching time at these sites in order to receive IME and GME payments for nonhospital rotations. If teaching hospitals, however, are no longer able to claim the time spent in these educational activities, how will they be able to continue to fund these important components of the graduate medical education process? The community hospitals will likely be unable to afford to continue funding graduate medical education.

Significantly, FAH would also like to point out the increased burden that will be created to residents and to teaching hospitals in documenting and tracking the time spent in didactic sessions – time that could have been spent in caring for patients. To require further documentation upon a group of young physicians who are already overburdened with paperwork and long work hours, adds no value to patient care, the educational process, or the ability to encourage students to enter the field of medicine. FAH believes that CMS's "clarification" will, in fact, increase the documentation burden by requiring hospitals/residency programs to track didactic time in large part because CMS has never previously formally published any policy on didactic time. Thus, FAH respectfully suggests that CMS is not clarifying policy but is instead setting forth a new policy for the first time.

IV.J. EMTALA

1. General Comments

The Proposed Rule also includes proposals by CMS to revise the EMTALA regulations. The proposals are based upon recommendations made to CMS by the EMTALA Technical Advisory Group ("TAG"). The FAH supported the establishment of the TAG as part of the

Medicare Modernization Act of 2003. The FAH has submitted testimony to the TAG and looks forward to participating in its future work.

Although the TAG's work is not yet complete, we support CMS' consideration of the TAG's recommendations as they are issued. We applaud CMS' decision to propose regulatory policies adopting these important TAG recommendations and urge CMS to continue to work with the TAG to address problems as they are identified so, where appropriate, EMTALA policies can be improved at the earliest opportunity. By working together, CMS and the TAG can clarify hospitals' obligations under EMTALA and ensure greater access to emergency health care services for all patients.

3. Definition of "Labor"

The EMTALA TAG recommended that the regulatory definition of "labor" be revised to permit certified nurse-midwives and other qualified medical personnel to certify false labor. Specifically, CMS proposes to revise the regulation at 42 C.F.R. § 489.24(b) to state that, "A woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital medial staff bylaws and State law, certifies that, after a reasonable time of observation, the woman is in false labor."

The FAH supports CMS' proposed revisions to this regulation. Such an approach recognizes the diverse nature of hospital bylaws which are based upon particular scopes of practice governed by state laws and regulations. Moreover, this change provides hospitals with the staffing flexibility that will help ensure necessary access to critical obstetrical services, particularly in rural and other areas where it may be difficult to recruit physicians.

4. Application of EMTALA Requirements to Hospitals without Dedicated Emergency Departments

The TAG recommended that hospitals with specialized capabilities should be required to accept transfers under EMTALA regardless of whether they have a dedicated emergency department. The TAG received testimony that physician-owned limited service hospitals often seek to avoid such transfers when they do not operate a dedicated emergency department by arguing that EMTALA does not apply to them. FAH is pleased that CMS has accepted the TAG's recommendation by proposing to modify the regulation at 42 C.F.R. § 489.24(f) to specify that any participating hospital with specialized capabilities or facilities, even those without a dedicated emergency department, may not refuse to accept an appropriate transfer if the hospital has the capacity to treat the individual. FAH strongly supports this proposed policy and urges CMS to adopt this approach in the final rule. In the final rule, we also urge CMS to provide additional guidance on the definition of "specialized capability or facilities." It is important to further define these terms so that EMTALA policies foster the critical involvement of physician-owned limited service facilities that CMS expects. In this regard, CMS should also emphasize that all physician-owned limited service facilities, even those that do not operate dedicated emergency departments, are expected to maintain adequate on-call panels to comply with the requirements imposed by Medicare's Hospital Conditions of Participation.

The FAH believes the transfer proposal is an important first step toward enhancing the ability of every community to serve the needs of emergency patients. However, it is unlikely that, even if finalized, this clarification will result in improved access to specialty care. Many limited service hospitals have limited hours of operation and are not "open" for patients seven days a week. If a physician-owned limited service hospital is closed, we are concerned that CMS will not consider the hospital to have had the capacity to treat patients and, therefore, the patient needing specialized services will still be cared for by the full service general hospital who has determined that a transfer is appropriate. This emphasizes a long standing concern with physician-owned limited service facilities: they don't function like full service acute care hospitals, either in hours of operation or availability of diverse service lines. Studies have shown that these facilities on average treat less acute patients and, therefore, are not well suited to deal with the complex emergencies that require specialized capabilities or facilities.

The current situation is clear that physician-owned limited service facilities rely heavily on their community's emergency services network while restricting the availability of on-call specialty physicians to serve the community's patients with emergency medical conditions. In our view, physician-owned limited service facilities should be required to provide their specialized services that they routinely offer to their patients around the clock, every day of the year. Otherwise, their presence will continue to hinder patient access to specialty care when those resources are not available at the community hospitals.

The truth is that those limited service facilities may not always have the ability to meet such a requirement. In such cases, CMS should require physician-owned limited service hospitals to have preexisting transfer agreements with any community hospital to which it may send patients for emergency services. CMS should specify the requirements of such a transfer agreement, which should be applied to all patients. CMS should also require physicians who practice at limited service hospitals to support robust emergency capacity at their community hospitals by requiring them to participate in on-call panels at those community hospitals. In developing regulatory policies, CMS should take necessary steps to ensure all patients have access to appropriate emergency care when they need it most.

Although supportive of CMS' transfer proposal, we are compelled to note that the proposal does not address the general problem of physician on-call shortages experienced by FAH members across the United States. While the foregoing recommendations seek to address the on-call crisis in those communities with limited service hospitals, the on-call crisis is bigger than that and must be addressed by CMS more globally to foster and protect access to care for Medicare beneficiaries. While the TAG is considering this issue, the FAH is concerned that any recommendations the TAG may make to CMS will not be adequate to address what is one of the greatest health care problems in the United States today.

IV.M. TRANSPARENCY OF HEALTH INFORMATION

The Secretary is "seeking comment on any ways in which the Department can encourage transparency in health care quality and pricing whether through its leadership on voluntary

initiative or through regulatory requirements. We are also seeking comment on the Department's statutory authority to impose such requirements." 71 Fed. Reg. at 24121. The FAH concurs with and supports the Secretary's desire that all health care consumers have access to relevant information so that they can select their health care providers and professionals based on valid and transparent measures of quality and meaningful pricing information, in particular out-of-pocket expenses, which insurers our best positioned to provide. For the reasons set forth below, the FAH: (1) pledges its support and continued participation in the Secretary's efforts and other local, regional and national efforts to make meaningful quality of care information available to health care consumers; (2) offers its analysis of the Secretary's rulemaking authority on the issue of the dissemination of pricing information; and (3) provides its continued support of voluntary efforts to make relevant pricing information available to consumers and various initiatives that have developed at the state level where local regulators, health care professionals, providers and, in particular, insurers, are better positioned to determine the parameters of pricing information provided to the mix of privately insured patients and those consumers responsible for the entirety of their health care costs.

1. The Dissemination of Health Care Quality Information.

The FAH and its members have been at the forefront of voluntary efforts to develop quality measures and disseminate that information meaningfully to consumers. The Hospital Quality Alliance (HQA) was formally launched at a press conference held by several public and private sector organizations December 12, 2002. It now includes the following groups as part of the public-private partnership focused on voluntary public disclosure of hospital quality performance:

- AARP
- AFL-CIO
- Agency for Healthcare Research and Quality (AHRQ)
- America's Health Insurance Plans
- American Hospital Association
- American Medical Association
- American Nurses Association
- Association of American Medical Colleges
- Blue Cross and Blue Shield Association
- Centers for Medicare and Medicaid Services (CMS)
- Consumer-Purchaser Disclosure Project
- Federation of American Hospitals
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- National Business Coalition of Health
- National Association of Children's and Related Institutions
- National Quality Forum
- U.S. Chamber of Commerce

As agreed to early in the process, a primary goal of the Hospital Quality Alliance is the creation of one set of commonly agreed upon measures that provide a broad picture of hospital quality and that are used by purchasers, oversight organizations, health care providers, and

consumers. An equally important goal was to establish a level of predictability for hospitals facing competing demands to report quality performance measures by multiple stakeholders. The FAH's Board of Directors discussed a broad outline of the initiative at its October 2002 meeting, and agreed to support the program and encourage its members to participate.

The first publication of the "starter set" of 10 quality measures occurred in October 2003. FAH member hospitals were well represented and recognized leaders of the initiative, and had a disproportionately high level of participation in the voluntary reporting.

The voluntary nature of the reporting program changed with the passage of the Medicare Modernization Act in December 2003. While still voluntary, the law allowed CMS to pay acute care hospitals a full market basket payment beginning October 1, 2004 if they reported all 10 quality measures before that time. On October 1, 2005, 96 percent of all inpatient PPS hospitals qualified to receive full market basket payment for FY 06 based on passing a medical record chart audit validation process at the 80 percent or higher rate of accuracy. As a consequence of section 5001 of the Deficit Reduction Act of 2005 (DRA), the Secretary was authorized to increase the number of quality measures that hospitals must report to procure the full market basket payment increase and, effective with fiscal year 2007, a hospital that fails to report such information will lose two percent of any such increase. Hospitals have more than sufficient incentive to report relevant quality measure information. The DRA also includes a provision under which the payment a hospital receives for certain DRGs will be reduced when a patient contracts an infection while in the hospital.

Since first publishing the quality data in October 2003 on a CMS website intended for health care professionals, CMS led efforts to identify ways to communicate the same clinical information to the general public in a meaningful way. On April 1, 2005, *Hospital Compare* was launched at a press briefing held by leaders of the initiative, including Dr. Mark McClellan, Administrator of CMS. At that time, Hospital Compare included two quarters of 2004 data on the ten initial measures and one quarter of 2004 data on seven additional measures included in the AMI, heart failure and pneumonia measure sets. Since then, Hospital Compare has been updated twice; in March 2006 it was updated to include the first two quarters of 2005 data. Twenty-two measures are currently reported to CMS and twenty of them are reported on Hospital Compare.

The FAH actively supports CMS's efforts with Hospital Compare. The quality information provided to Medicare beneficiaries is directly relevant to the very personal choices they make in selecting their health care providers and, ultimately, their health care professionals. The FAH looks forward to assisting in further improvements to this valuable tool by making the information therein more understandable and relevant to all those in need of health care services.

2. CMS's Rulemaking Authority to Require the Production and Dissemination of Pricing Information by Hospital.

The FAH does not question CMS authority to publish Medicare payment rates at a hospital specific level. That is one alternative identified in the proposed rulemaking. In fact, that alternative was implemented by CMS on June 1, 2006 with the publication of Medicare pricing information for 30 common procedures by hospital aggregating all Medicare payments

applicable to that hospital, including any patient copayments. CMS also published the average national charge for such procedures along with the average national Medicare payment. While the publication of this information may be desirable for some, for example as a benchmark for comparative purposes, it has limited, if any utility in other contexts.

As a practical matter, Medicare beneficiary out-of-pocket costs have no correlation to anything based on inpatient DRG or outpatient APC payments. A Medicare beneficiary's co-payments are fixed for virtually all services provided on an inpatient and outpatient basis. Thus, the information has limited value for the population for which CMS is directly responsible. The information also would have limited utility to non-Medicare beneficiaries because their out-of-pocket payments bear no relationship to DRG payments paid by CMS on behalf of Medicare beneficiaries. Additionally, Medicare payment rates in a given market are relatively similar amongst like hospitals in that market such that it would not provide information that would allow consumers to shop for services. Conversely, teaching hospitals and qualifying Medicare disproportionate share hospitals can have widely variable payment rates depending on their mix of residents, bed size and number of low income patients being treated. As such, consumers are likely to be unable to decipher the valid reasons for wide Medicare payment variances when comparing prices for hospital services.

Given that CMS has elected such an option before comments were even submitted, the FAH believes that how such pricing information is characterized by CMS on its website is vital to ensure that the information is properly used by the public. There currently is no link associated with this CMS payment information that educates the public about how Medicare pays hospitals, explains the components included in the identified payments, how payments may vary by hospital in a region that have little to do with a hospital's efficiency, how payments may vary for similar conditions or how the information should be used in making care choices. Indeed, CMS does not even indicate that such payments for every hospital in the country are established by statute or regulation and the hospitals have no control over the amount of such payments.

The FAH has cause to be concerned with how the public will view and use this payment information. For example, within 24 hours of publication of this information by CMS, at least one national institute for health and tax policy, the Galen Institute, published the following statement on its website: "There are also big pricing differentials when you drill down into the data. ... You see that a valve replacement could cost as little as $26,600 in Schenectady, NY, but more than $68,000 in Hardin County, KY." Galen Institute, Transitions and Transformations, June 2, 2006, 11:43 AM, copy provided herewith as Exhibit C. The article intimates consumers can shop based on this information when in fact hospitals do not set these payment rates. It is true that these payments are a cost to the Medicare program, but they do not represent consumer costs and are not based on hospital pricing. If CMS desires to publish such information it needs to make such facts clear and it needs to identify how consumers, if at all, can benefit from this information.

While the FAH does not question CMS's authority to publish Medicare pricing information, the FAH does not believe that Congress has conferred any authority on the Department of Health and Human Services or the sub-agencies there under, including CMS, to compel hospitals to produce and identify charging information applicable to non-Medicare

beneficiaries. The Department has various sources of rulemaking authority including the general authority to administer the Medicare program set forth in 42 U.S.C. § 1395hh, and the limitations set forth at 42 U.S.C. § 1302, and specific authority conferred by Congress for new initiatives under the Medicare program.

We can find no support in the general authority under sections 1302 or 1395hh that would allow the Secretary to compel hospitals to release non-Medicare pricing information to the general public. Section 1302 is a general grant of authority to the Secretary to administer federal health programs, but contains special requirements for any rulemaking efforts that have a significant impact on a substantial number of small rural hospitals. The true source for the Secretary's rulemaking authority under Medicare is set forth at section 1395hh, the section the Secretary almost universally cites for its rulemaking authority, including for example, the Medicare conditions of participation. Section 1395hh provides in relevant part:

> **(a)(1)** The Secretary shall *prescribe such regulations* as may be *necessary to carry out the administration of the insurance programs under this title*. When used in this title, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.
>
> **(a)(2)** No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the *scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title* shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1). [Emphasis added.]

Under section 1395hh the Secretary's authority to issue rules is limited to only those necessary to carry out the administration of the federal insurance programs. Those functions subject to a formal rulemaking requirement include the items contained in section 1395hh(a)(2), none of which could be read to require the publication of information by hospitals that is designed to benefit persons *that are not beneficiaries of the federal insurance programs over which the Secretary has authority*. Thus, the Secretary's suggestion in the Proposed Rule that Medicare conditions of participation could be modified to require hospitals to publish non-Medicare payment data does not fall under the ambit of authority conferred by section 1395hh. Indeed, such a position by CMS would arguably diminish access for Medicare beneficiaries to otherwise qualified providers because of a participation criteria that does not even benefit Medicare beneficiaries.

While Congress could certainly legislate to require hospitals to produce pricing information unrelated to federal program beneficiaries, it has not yet chosen to do so. For example, section 5001(a)(3) of the DRA requires the Secretary to report cost of care information associated with Medicare on its website, which is arguably satisfied by the Secretary's June 1, 2006 publication of hospital Medicare payment rates.

The FAH believes that the best path to pursue on price transparency is a blend of voluntary public-private initiatives at the national level with existing and evolving local industry efforts and, importantly, an increasing number and variety of programs at the state level. All of

these activities should be carefully monitored before decisions, which could disrupt this marketplace of ideas, are made on whether and how to intervene at a national level.

3. Voluntary and State Efforts to Provide Meaningful Pricing Information to Consumers.

Currently there is considerable interest and public discussion concerning hospital and physician charges and whether these charges can be easily understood by patients. The questions arise principally due to the large number of separate items and services with charge amounts – for example, hospitals' charge masters typically include more than 25,000 items – and because billed charges reflect gross amounts that do not reflect the discounts received (or imposed) by public and private insurers. Interest in charge levels is particularly high from two perspectives: the uninsured (especially the low-income uninsured) and individuals enrolled in high deductible plans like HSAs and HRAs.

In response to the plight of the uninsured and low income patients with insurance (including Medicare beneficiaries), members of the FAH were the first in the country to work through the significant legal issues associated with discount programs with CMS and offered system wide discounts to those in need, some with a sliding scale that varies with income levels. Many hospital discount programs do not charge patients at all for services when a patient's income falls at or below 200% of the federal poverty level or discount such services to as little as 20 percent of charges. Some hospitals base discount percentages on aggregate negotiated managed care rates, voluntarily providing consumers access to pricing negotiated by those with far more market leverage than individual patients, and not federally controlled and mandated pricing levels as is the case with Medicare payment rates. Hospitals have stepped in to assist the uninsured, but the responsibility for a remedy must be shared with a larger group that includes employers, the government and insurers.

The FAH believes hospitals should continue to have flexibility in determining the nature of such discounts based on local patient demographics and their ability to afford discounts. The FAH opposes mandating discounts to the uninsured population, including those tied to Medicare rates, because such mandates would not provide the flexibility necessary to take into account local community needs, the hospital's financial condition or other hospital fiduciary responsibilities. Most hospitals provide information regarding such discount programs in their admitting office where patient eligibility for such discounts can be determined by personnel that are experienced in the complexities of hospital pricing. Additionally, some hospitals make such discount program information available on the hospital's web site.

Fueled by this interest in allowing health care consumers to shop for services, many states, insurers, hospital associations and others are taking steps to make more user-friendly information available to the public as revealed by an "environmental scan", recently conducted by FAH, of current state and insurer efforts. Key results are highlighted below.

In the late 1990s a few states, including Washington and Massachusetts, started publishing the average "billed charges" for the most frequently occurring DRGs. It was not until the emergence and promotion of health savings accounts (HSAs) and elevated concern about the uninsured that a growing number of states began amending their hospital reporting requirements

to include "price transparency" type provisions. While the accounting is incomplete, at least seven states have recently adopted legislation intended to promote hospital price transparency including California, Florida, Illinois, Maine, Nevada (refinement of existing law), and South Dakota.[2] Several state hospital associations have established programs to make pricing data available including Wisconsin, Oregon and New Mexico (the latter two have licensed the Wisconsin PricePoint program, which is discussed below).

Some of the common characteristics of these "price transparency" programs include:

- All programs target hospital inpatient services and many include hospital outpatient and ASC services;
- A few programs exempt small, rural hospitals;
- Concerning physician services, few, if any, state reporting and disclosure programs include physicians (but physicians are included in some insurer programs, as noted below);
- Typically, the programs require quarterly submissions;
- Hospitals are required to submit data ("claims and encounter data for each patient") sufficient to enable a comparative analysis of average or median "charges", by DRG or procedure;
- In some programs, the "average charge" included the negotiated rates paid by health plans;
- Most laws include broad discretionary language to allow the collection of all "information as is necessary to enhance decision making among consumers and health care purchasers;"
- Typically, the law provides for the inclusion of providers, etc., in the development of the methodology for collecting, analyzing, and disclosing the information;
- Public disclosure reports, typically web-based, included the average/median charge for a given number (25 to 60) of DRGs;
- In same cases, charges are presented by a range – low and high;
- Averages for peer groupings, by region and state, for a particular DRG/procedure are also usually provided;

[2] There are at least five other states with legislation pending including Colorado, Georgia, Kansas, Nevada, and Ohio.

- All of the programs reported aggregate information, i.e., the programs generally did not separate Medicaid, Medicare and commercial payors. The Wisconsin Hospital Association's "PricePoint" appears to be the only one to show the percentage of aggregate payments to total charges for Medicare, Medicaid, and private payor, respectively; and

- Some, not all, programs include some risk adjustment/reflection factor. Florida, for example, allows patients to find out risk-adjusted charges for a variety of procedures.

It is not surprising that current state reports do not include the payment rates each health plan negotiates with the respective hospital because from the subscriber's standpoint, the main concern is the co-insurance and deductible (i.e., how much will I have to pay?), rather than how much the health plan pays the hospital, since that payment "doesn't come directly out of their pockets." However, it is surprising that none of these programs focuses on aspects of transparency involving physician ownership in specialty hospitals, so that members of the public become aware that a physician ordering a service or suggesting an admission to such a facility has an ownership interest in the entity to which the patient is being referred. That is an important element of transparency that should be part of any responsible program.

The Wisconsin Hospital Association's "PricePoint" program forms the beginnings of how a consumer-friendly and value-added program could work. It not only provides charge information for common DRGs but also cites the average percentage of charges hospitals actually received from Medicare, Medicaid and private payors. For example, for Providence Portland Medical Center, payments from private insurance covered 64 percent of charges for the year ending August 31, 2005. Reporting average and median charges for the entire admission avoids the minute detail of charge master data. The other side of the reporting coin is quality, and a partnership between the Wisconsin Collaborative for Healthcare Quality (WCHQ) and the WHA, launched in May, also puts detailed quality information on the Web. Called Healthclick Wisconsin, the site links quality initiatives sponsored by the two organizations on one site: the WHA's CheckPoint and the WCHQ's Performance and Progress Report. An uninsured patient with access to PricePoint and local hospital discount program information could potentially make out-of-pocket cost comparisons for common procedures. However, PricePoint may be less useful to insured patients, including those with an HSA, because it cannot relate pricing data to an insured patient's out-of-pocket costs. The low cost hospital from a charge perspective may be the more expensive provider for an insured patient because of the lack of a contractual agreement between that hospital and the relevant insurer, or because the hospital is not a preferred provider with the insurer.

California's 2003 law requires hospitals to disclose the price of 25 common procedures and their highly detailed hospital "chargemasters." This effort, however, suffers from these problems and limitations:

- There are no standard definitions for the procedures, so prices among hospitals aren't comparable. For example, at least one hospital included professional fees in X-ray charges while others did not.

- The chargemaster information is provided in raw, highly detailed and very technical form. Consumers are unlikely to be able to understand even what item or service the charge references unless they posses detailed medical knowledge.

- Data are not posted on a website. Consumers must pay $10 to obtain the data on CD-ROM.

- The chargemasters contain list prices, but such prices are rarely paid. Low-income patients and occasionally other self-pay patients often can get discounts.

It is also important to note that insurers are implementing a variety of ways to help consumers make better purchasing decisions. Insurers enjoy a comparative advantage in terms of pricing information because they maintain databases of charges and actual amounts paid for their enrollees. Insurers are also best positioned to reveal to the enrollee the expected costs for an entire episode of care, beyond the hospitalization. At this point, Aetna, Cigna, Humana, PreferredOne and Healthcare Direct LLC have programs that show members their potential out-of-pocket costs. In addition, many of these insurers also provide its members estimated market pricing (i.e. combined plan and member costs) for certain commonly performed hospital procedures. The Blue Cross and Blue Shield Association announced a new initiative on June 8, 2006, called Blue Distinction, promising an "unprecedented level of transparency" for consumers. Nevertheless, to the extent many plan member's out-of-pocket costs are capped, the value of this pricing transparency is diminished.

In at least one key respect, the situation is similar for HSA account holders, the majority of which use their accounts to purchase high deductible catastrophic coverage. An April 2005 survey of HSAs, commissioned by the FAH and the American Hospital Association, showed that 95 percent of enrollees had access to existing networks and negotiated rate structures with hospitals. What that means is that, like holders of traditional insurance products, virtually all HSA account holders can look to their insurer for comparative pricing information. However, while the deductible amounts for such policies can fall in a range of $2000-$5000, because these are the first dollars paid for a service, pricing information is unlikely to have as significant a benefit to HSA holders who consume inpatient services. These first dollar high deductibles will almost always have to be paid in full by the consumer for an inpatient stay irrespective of the level of a hospital's charges, which may limit meaningful shopping for those with HSA accounts based on price. If one of the overriding goals of pricing transparency is to permit competitive market forces to dampen healthcare inflation then the fact that HSA consumers may very well pay their full deductible for inpatient hospital stays weakens this pricing transparency goal.

What is certainly true based on the information pooled from the efforts of insurers is that insurers are in the best position to advise a patient about what matters most to them — their out-of-pocket costs, and total episode of care costs. To the extent that the uninsured can become insured, they can become better consumers armed with sufficient information to make choices about their health care needs.

All of these price transparency programs are in the nascent stages of development and will need time to work through implementation and relevancy issues. These programs are the laboratory from which a useful pricing transparency program will evolve. They evidence a vibrant pricing marketplace that exists now for hospital services, driven by insurers and other payors, refuting the assertion in the proposed rule that "providers of care are not subject to the competitive pressures that exist in other markets..." Indeed, FAH cautions against federal efforts that would interfere with this pricing marketplace. For example, implementation of a proposal like the Office of Inspector General's 2003 proposed rule on charges would likely interfere with hospital price-setting practices in the marketplace and could conceivably function as a government-set price control. FAH stands ready to work with the Administration on a voluntary public-private effort focusing on price transparency.

IX. LIMITATION ON PAYMENTS TO SKILLED NURSING FACILITIES FOR BAD DEBT

Through a proposed revision to 42 C.F.R. § 413.89, CMS is implementing the DRA § 5004 mandate to reduce allowable bad debt by 30% for beneficiaries treated in skilled nursing facilities who are not "full benefit dual eligible" as defined in 42 C.F.R. § 423.772. The FAH notes that in response to DRA § 5004, the freestanding skilled nursing facility cost reporting Form 2540-96 has already been revised pursuant to Transmittal 14, dated April 2006. However, the corresponding hospital cost reporting form for distinct part skilled nursing facilities, Form 2552.96, has not been revised.

Section 5004 of the DRA states only that the 30% bad debt reduction applies to skilled nursing facilities. There is no specific distinction made or drawn between freestanding skilled nursing facilities and distinct part unit skilled nursing facilities.

Therefore, the FAH asks CMS to clarify its application of the proposed 30% bad debt reduction to skilled nursing facilities in 42 C.F.R. § 413.89(h)(2) with respect to whether the reduction applies only to freestanding skilled nursing facilities, as opposed to distinct part unit skilled nursing facilities, or to both. If the reduction applies only to freestanding facilities, then no further revision of the cost reporting forms is required to implement this change. However, if the 30% reduction is to be applied to distinct part skilled nursing facilities units as well, Form 2552-96 should be revised as soon as possible, so as to minimize any necessary revisions by providers to cost reporting information throughout the remainder of each skilled nursing facility's cost reporting year.

The Proposed Rule also states that the 30% reduction does not apply to beneficiaries who, for any month, are defined as "full benefit dual eligible individuals" as defined in 42 C.F.R. § 423.772. The definition of a full benefit dual eligible individual means an individual who, for any month, (1) "has coverage for the month under a prescription drug plan under Part D of Title XVIII, or under a MA-PD Plan under Part C of Title XVIII;" and (2) "is determined [to be] eligible by the State for medical assistance for full benefits under Title XIX for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under Section 1115 of the [Social Security] Act. (This does not include individuals under Pharmacy Plus program demonstrations or under a Section 1115 demonstration

that provides pharmacy-only benefits to these individuals.) The definition also includes any individual who is determined by a state to be eligible for medical assistance under Section 1902(a)(10)(C) of the Social Security Act (medically needy) or Section 1902(f) of the [Social Security] Act (states that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month."

The FAH notes that Medicare Provider Reimbursement Manual, Part I, Section 322, states, in pertinent part:

> Where the State is either obligated either by statute or under the terms of its plan to pay all, or any part, of the Medicare deductible or co-insurance amounts, those amounts are not allowable as bad debts under Medicare. Any portion of such deductible or co-insurance amounts that the State is not obligated to pay can be included as a bad debt under Medicare, provided that the requirements of Section 312 or, if applicable, Section 310 are met.

The FAH notes that together with the newly proposed federal regulatory provisions, an additional administrative burden will be imposed under Section 322, above, on skilled nursing providers to try to identify those beneficiaries who may, as a result of Section 322, either be or not be considered "full benefit dual eligible individuals," to assure that the reduction percentage is applied properly. The FAH believes that this new requirement places skilled nursing providers at an increased risk of potentially overstating bad debts as a result of a lack of documentation supporting the beneficiaries' benefits. At this point, it may be difficult for providers to obtain the necessary documentation regarding the extent to which an individual is deemed eligible by a state for medical assistance for full benefits under the Medicaid program where the individual is also participating under Part D of the Medicare program.

The FAH wishes to make CMS aware of these potentially increased burdens and the potential pitfalls faced by individual SNF providers in seeking to comply with this limited application of the 30% reduction in bad debt payments in the case of full benefit dual eligible individuals. In addition, the FAH requests CMS assistance in seeking to minimize such additional administrative burden.

ADDENDUM: OPERATING PAYMENT RATES

1. Exclusion of CAH Wage Data.

The FAH has been informed that the Connecticut Hospital Association has raised a concern about the impact of excluding wage data for Critical Access Hospitals (CAHs) from the wage index file. We understand that the Association believes that the exclusion of this data is resulting in an understatement of wage indexes throughout the country and will result in an underpayment to IPPS hospitals of approximately $500,000,000 for FY 2007. Because this concern has been raised, the FAH would like to see it addressed in the Final Rule. The FAH has

reviewed the description given of the budget neutrality adjustment, which presumably would account for the removal of the CAH wage data, but the Proposed Rule gives insufficient detail for the public to determine whether the budget neutrality adjustment has properly taken this into account.

2. **Outliers**.

CMS has proposed to establish the fixed-loss cost outlier threshold for FY 2006 as the prospective payment rate for the diagnosis related group ("DRG"), plus any indirect medical education ("IME") and disproportionate share hospital ("DSH") payments, and any add-on payments for new technology, plus **$25,530**. The present threshold, which has been in effect for all of FY 2006, is $23,600. In establishing the proposed FY 2007 threshold, CMS has proposed using the "charge methodology" that it began using for FY 2003, as modified last year when developing the FY 2006 threshold. This "refined methodology" takes into account the lower inflation in hospital charges that has occurred in recent years, since the outlier methodology was revised to use more current and accurate cost-to-charge ratios ("CCRs"). As part of its calculation for the FY 2007 thresholds, CMS is proposing to calculate the 1-year average annualized rate-of-change in charges-per-case from the last quarter of FY 2004 in combination with the first quarter of FY 2005 (July 1, 2004 through December 31, 2004) to the last quarter of FY 2005 in combination with the first quarter of FY 2006 (July 1, 2005 through December 31, 2005). According to CMS the average annualized rate-of-change in charges per case between these periods was 7.57 percent, 15.15. percent for two years. [3] Also, as in years past, CMS has proposed to use the hospital cost-to-charge ratio from the most recently available Provider Specific File, which for FY 2007 is the December 2005 update.

CMS has proposed to establish the FY 2007 threshold using the same model as was used for FY 2006. In its comments last year (as in the prior year), the FAH objected to CMS's proposed methodology, contending that the model being used by CMS would severely underreimburse hospitals for their outlier payments. Despite CMS's tweaking last year of the method for estimating the rate-of-increase in charges, the FAH's projection has turned out to be true. While not as huge as in the previous two years, there is going to be a significant outlier shortfall in the current fiscal year. For FY 2006, CMS has stated in the Proposed Rule that it estimates that outlier payments will be 4.71 percent of actual total DRG payments, 0.39 percent lower than the 5.1 percent that CMS projected when setting the outlier thresholds. This shortfall represents an aggregate underpayment of approximately $327 million. This comes on the heels of the large shortfalls that occurred in the previous two years. According to CMS's estimates, outlier payments were only 3.5 percent of total actual PPS payments during FY 2004 and were only 4.1 percent of total actual PPS payments during FY 2005.

Though the FAH acknowledges that there was some improvement in CMS's projection last year as compared to the two previous years, it is clear nonetheless from the experience of

[3] While CMS states that the two year inflation factor to be used will be 15.15 percent, this is not consistent with the annual inflation factor of 7.57 percent that is stated in the Proposed Rule. The annual inflation rate of 7.57 percent translates into a 15.71 percent two-year rate. The 15.71 percent rate has been used for the modeling discussed in these comments.

these past three years that CMS's methodology to project outlier payments and set the outlier thresholds is not working. Thus, CMS has significantly under paid outliers every year since it adopted the "charge methodology". The FAH is especially concerned because CMS has proposed to raise the outlier threshold for FY 2007, which, based on past experience, will result in the continued underpayment of outliers below the 5.1% target. The FAH urges CMS to recognize the fact that its "charge methodology" unadjusted to recognized charge and cost increases in computing the CCRs have led to shortfalls for the past three years and to consider altering its methodology so that more accurate projections can be made.

The FAH believes that the model that CMS has used for FYs 2004, 2005 and 2006, and has proposed to use again for FY 2007, fails to incorporate one extremely significant variable: the resulting decline in the CCR that is a by-product of significant projected charge increases. As the FAH has pointed out repeatedly in past comments, the objective of the outlier model should be to project outlier costs. The present CMS model using the two year average annualized rate of change in charges per case based on two recent six month periods, but with the CCR locked as of December 2005, will fail to reasonably project outlier costs, as proved in previous years. Outlier costs are equal to charges times CCR. CMS is projecting the charges to increase for FY 2007 by 15.15 percent over 2 years[4]; yet, the CCRs are locked to fiscal periods beginning in Federal Fiscal Year 2004 or even earlier. Such a model will invariably underpay outliers. The FAH urges CMS to consider alternate models, discussed herein, which should, as confirmed by past projections, lead to a more accurate projection of outliers.

As was done in support of its comments for the past few years, the FAH engaged Vaida Health Data Consultants ("VHDC") to model the outlier thresholds for FY 2007 using CMS's proposed 2-year charge increase model, modified to reflect the decline in CCRs. The FAH has attached as Exhibit D to this letter a copy of the outlier study ("Modeling FFY 2207 Outlier Payments") performed by VHDC for the FAH. Based upon that model, the outlier threshold should be set, at an absolute maximum, at **$24,000**.[5]

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[4] The FAH believes that the amount of outlier payments paid out in FY 2005 may have been overstated by CMS in the Proposed Rule. The figure given , 4.1 percent, is the same figure that was given in last year's Final Rule; it is unusual that there would not be some adjustment based on more recent data. The FAH's consultant, Michael Vaida, has checked CMS's calculations based on available data and has determined that a more accurate estimate of outlier payments for FY 2005 would be 3.8 percent. The FAH urges CMS to recheck its calculation.

[5] It should be noted that this figure was calculated using the CMS's projected charge inflation estimate (i.e., 7.57 percent per year) as stated in the Proposed Rule. It is likely that updated data will result in a decrease in this estimate by the time that the Final Rule is published. (The projected charge inflation estimate of 8.65 percent in the Proposed Rule for FY 2006 was reduced to 7.21 percent when the Final Rule for FY 2006 was published.) Assuming there is a decrease in this estimate of charge inflation, the outlier threshold that would be projected using the methodology described herein, using charge inflation and also taking into account the projected decrease in CCRs, would be lower than $24,000.

CMS recognizes that CCRs are declining as a result of increases in charges exceeding cost increases. In the Proposed Rule on page 24150 of the Federal Register, CMS states:

> We note that the case-weighted national average cost-to-charge ratio declined by approximately 1 percent from the March 2005 to the December 2005 update of the Provider-Specific File. Hospital charges continue to increase at a steady rate of growth between 7 and 8 percent over each of the last 2 years, resulting in a decline to the cost-to-charge ratios that are used to compute the outlier threshold.

Despite recognizing the decline in the CCRs caused by the fact that charge increases have been exceeding cost increases, CMS has continued to use the "charge methodology" without recognizing this decline. The FAH urges that CMS adopt the modification to the "charge methodology" that FAH has consistently recommended.

Significantly, the FAH notes that the projections for FYs 2004, 2005 and 2006 that would have resulted from VHDC's suggested modified charge inflation methodology would have been considerably closer to the thresholds that would have resulted in the 5.1 percent target being met than were the projections done by CMS for those three fiscal years. In its comments for FYs 2004, 2005 and 2006, the FAH modeled the 2-year charge increase model that was used by CMS, but recommended that CMS also model the decline in the CCRs rather than locking in the CCRs at a point in time. Using the projected decline in CCRs, VHDC's model for the outlier threshold resulted in a threshold of $25,375 for FY 2004, This was in contrast to the threshold of $31,000 (revised downward midyear to $30,150) adopted by CMS, which resulted in outliers paid at the 3.5 percent level, representing a staggering 34 percent, or $1.4 billion, underpayment. Although still resulting in a threshold that would have been too high, VHDC's projected threshold of $25,375 using this model would have been considerably closer to $21,555, where the threshold would have to have been set to reach the 5.1 percent target.

For FY 2005, VHDC's model resulted in a threshold of $28,445, compared to the CMS projected threshold of $35,085 set forth in the proposed rule for FY 2005 (which would have been $32,510 if CMS had used the 3/31/04 HCRIS update that VHDC had used). While CMS reduced the threshold in its Final Rule to $25,800, this resulted from the significant decline in CMS's projection of charge inflation (from 14.5083 percent per year to 8.9772 percent per year). If VHDC had used this lower estimate of charge inflation and plugged it into its methodology that took into account the projected decline in CCRs, it would have calculated a threshold that would have been significantly lower than the revised CMS threshold. VHDC has calculated the threshold now, using the reduced charge inflation estimate that was used by CMS when it calculated the threshold for the Final Rule. This resulted in a fixed loss amount of $24,200. *See* "Estimate of the FFY 2005 Fixed Loss Amount Projecting Both Charge and Cost Inflation," attached as Exhibit E.[6] While CMS's threshold ($25,800) resulted in outlier payments at only the

[6] VHDC performed this calculation using the version of MedPAR that was available at the time that the proposed rule was published. While CMS calculated its outlier threshold for the final rule using a more recent version of MedPAR, VHDC does not currently have access to that (footnote continued)

3.8 percent level (assuming VHDC's calculation of the amount actually paid for FY 2005 is correct), the threshold that would have been derived using the VHDC methodology ($24,400) would have been lower and would have been much closer to the level needed to reach the 5.1 percent target.

For FY 2006, VHDC's model resulted in a threshold of $24,050, compared to the CMS projected threshold of $26,675 set forth in the proposed rule for FY 2006. While CMS reduced the threshold in its Final Rule to $23,600, this resulted from the use of updated data to determine the rate of increase in charges. Use of this updated data reduced the projection of charge inflation from the 18.04 percent used to calculate the thresholds in the proposed rule to a substantially lower amount of 14.94 percent. If VHDC had used this lower estimate of charge inflation and plugged it into its methodology that took into account the projected decline in CCRs, it would have calculated a threshold that would have been significantly lower than the revised CMS threshold and closer to the threshold level that would have resulted in 5.1 percent outlier payments.[7]

For FY 2007, VHDC, as explained in detail in the attached report (Exhibit D) at pp. 2-3, estimated what the fixed loss amount should be, using the same "charge methodology" used by CMS in its projections. VHDC ran several projections to demonstrate the impact of factors that should be taken into account but were omitted from CMS's projection methodology. First, VHDC ran a projection using the most recent (3/31/06) HCRIS update. This resulted in an estimated fixed loss amount of **$24,990** (compared to the $25,530 fixed loss amount projected by CMS.) Second, VHDC ran a projection that took into account the decline in CCRs that will occur before outliers are actually calculated during FY 2007. The decline in CCRs was projected from the most recent CCR data in the 3/31/2005 HCRIS update to the fiscal periods expected to be used for the calculation of the CCRs determining outlier payments during FY 2007. The projected decrease in CCRs was calculated using the CMS charge inflation factor of 7.57 percent and the 2002-2004 aggregate annual rate of increase in cost per discharge, calculated by VHDC to be 5.69 percent. This second projection, taking into account the key factor of updating CCRs, resulted in an estimated fixed loss amount of **$24,000**. Based upon this analysis performed by VHDC, the FAH recommends that CMS set the outlier threshold at no more than $24,000 for FY 2007.

As stated previously, the objective of the outlier model should be to reasonably project outlier costs. Thus, as the FAH did for its comments in the previous two years, it also asked VHDC to estimate the fixed loss threshold using the "cost methodology," rather than the "charge

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version. However, the use of these slightly different versions of MedPAR would not significantly affect the calculation.

[7] As part of its engagement, VHDC modeled what the threshold should have been to pay out the 5.1% for FY 2006. Since this fiscal year is not yet complete, this can only be an estimate based on currently-available data. VHDC estimated where the threshold should have been using various methodologies. *See* Exhibit D, pp. 4-5. According to VHDC's calculations, this would likely be in the range of $21,160 to $21,275, or perhaps slightly lower.

methodology." This was the methodology that CMS used for FYs 1994-2002. VHDC used the most recent cost data available, and it projected costs to FY 2007 using the cost inflation factor of 5.69 percent derived from HCRIS data for 2002, 2003 and 20004. CMS started utilizing the 2-year charge increase model beginning in FY 2003, largely due to the lack of timely cost report data resulting from the delay in filing of cost reports after the implementation of outpatient PPS. Prior to FY 2003, CMS utilized the cost model to project the outlier threshold, but, without timely cost report data for FY 2003, CMS was unable to continue using the cost model at that time. Now that the backlog in filing and processing Medicare cost reports has long been resolved, this methodology could be considered again (as the FAH has suggested for the past two years).

Using data from the recent 3/31/06 HCRIS update, VHDC ran projections using the cost methodology, which resulted in an estimated fixed loss threshold for FY 2007 of **$23,055.** If the most recent CCRs from the HCRIS database were used instead, the estimated FY 2007 fixed loss amount is **$22,645**.

The FAH notes that projections using the cost methodology have been much closer to the ultimate threshold needed to achieve the 5.1 percent target for the past few years than have been the projections done using any of the various charge methodologies. For FY 2006, VHDC's projection using the cost methodology resulted in a fixed loss amount of $22,520. This would still likely have been too high a threshold, but it was closer to the $21,160-$21,275 that VHDC estimates would have been appropriate to hit the 5.1 percent target than the thresholds projected by other methodologies. (*See* Exhibit D, p. 4 and the FAH's June 24, 2005 Comments on the FY 2006 Proposed IPPS Rule, at p. 51.) For FY 2005, VHDC, using the cost methodology, estimated that the outlier threshold should be set at $22,830. Of all projections, this, while still too high, was closest to the $19,790 that would have been necessary to reach the 5.1 percent target. (*See* Exhibit D, p. 5-6 and the FAH's July 8, 2004 Comments on the FY 2005 Proposed IPPS Rule, at p. 5.)

For FY 2004, the FAH did not present an estimation of the outlier threshold based on the cost methodology when presenting its comments on the IPPS proposed rule. However, last year, the FAH asked VHDC to retroactively calculate what the projected threshold would have been using the cost methodology as if he had done this at the time his report for FY 2004 was being prepared. Using this method, VHDC calculated a threshold of $20,900. (*See* Exhibit D to the FAH's June 24, 2005 Comments on the FY 2006 Proposed IPPS Rule, at p. 2.) VHDC also calculated that the actual threshold necessary to reach the 5.1 percent target for FY 2004 would have been $21,555. The projection using the cost methodology was closer to this amount than the projections made by CMS or by VHDC using its modified charge methodology. (*See* the FAH's June 24, 2005 Comments on the FY 2006 Proposed IPPS Rule, at p. 51-52.)

CMS is to be commended for the changes made to the outlier payment methodology in 2003 to eliminate the use of the statewide average for hospitals with low CCRs, to adopt the use of the most recent settled cost report to adjust the CCR, and to require the more timely update of the CCRs. While in the several years prior to FY 2003 the use of the cost methodology was resulting in outlier payments exceeding the 5.1% target, FAH believes that the corrective actions taken by CMS in 2003 significantly strengthen the predictability of the cost methodology Such excess payments prior to 2003 should not be attributed to the cost methodology, but should be

more likely be attributed to the untimely update of the CCRs and to the use of the statewide average for hospitals with extremely low cost-to-charge ratios.

Because the cost methodology, as shown herein, has proved to be a more accurate predictor of the correct outlier thresholds, the FAH recommends that CMS return to the use of the cost methodology for the projection of outlier payments. The FAH recommended this last year, but CMS chose not to follow the recommendation. Since there has now been a history of three years in a row confirming that the cost methodology is a better predictor of the correct thresholds, the FAH offers this suggestion even more forcefully than before. The cost methodology should be used, and the fixed loss outlier threshold should therefore be set at **$22,645**.

The FAH also suggests that CMS consider making mid-year adjustments to the outlier thresholds, if it appears that outlier payments are going to be significantly below or above the 5.1% target. As CMS made a mid-year change to the fixed loss threshold in FY 2004, it clearly has the ability to do so. After the fiscal year has begun, more current data on hospitals' cost-to-charge ratios will be available, so it should be possible to more accurately predict the amount of outlier payments that will be made. CMS could set a trigger for this adjustment. For example, if outlier payments appeared to be coming out at less than 95% or more than 105% of the 5.1% target, an adjustment would be made. The large discrepancies between outlier payments made and the 5.1% target, both positive and negative, that have occurred over the years could possibly be avoided if CMS tracked the situation mid-year and made an adjustment to the threshold with the goal of hitting the 5.1% target overall for the year. The FAH believes that a mid-year correction process could be an aid to CMS to achieve its goal of making outlier payments at 5.1% irrespective of the payment model that CMS employs. However, we believe there will likely be less need for a mid-year correction process if CMS were to adopt either of the two payment models that we have recommended in these comments, i.e., the cost methodology model or the CMS model modified to reflect the decline in the CCRs.

In summary, the FAH is extremely concerned with the continued use of the present CMS model that has proven to significantly underpay hospitals for outliers for FY 2004 and FY 2005. The CMS model does account for charge increases when modeling the MedPAR claims but fails to account for charge and cost increases when projecting the CCRs. Such a model will invariably continue to significantly under-reimburse hospitals for patient care services rendered to Medicare patients that become outliers. The FAH recommends that CMS either adopt the cost methodology that it used prior to FY 2003 or, in the alternative, adopt the model recommended by the FAH that adjusts for both charge and cost increases in computing the CCRs.

The FAH recognizes that many of the changes proposed by CMS for FY 2007 and beyond have required (and will continue to require) exhaustive efforts on the part of the CMS Administration and staff, providers, intermediaries and consultants on all sides. Many of these changes have the potential to lead to meaningful and positive developments for the Medicare program. FAH members want to assure, however, that changes of this magnitude are not rushed and that careful thought and consideration go into any final product. The FAH and its members appreciate the work CMS has done in preparing this Proposed Rule, and we want to work closely with CMS, in a truly cooperative spirit, to assure that the Medicare program functions smoothly, efficiently and fairly for many years to come in light of these changes.

Respectfully Submitted,

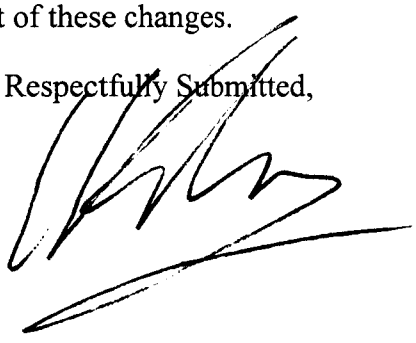

EXHIBIT A

EXHIBIT B

Inpatient Prospective Payment System (IPPS) Analysis for FY2007

Technical Appendix

Date: June 6, 2006

THE MORAN COMPANY

Table of Contents

Inpatient Prospective Payment System (IPPS) Analysis for FY2007
Technical Appendix

Date: June 6, 2006

I. Introduction

For the Federation of American Hospitals (FAH), American Hospital Association (AHA), and Association of American Medical Colleges (AAMC), The Moran Company (TMC) analyzed alternative methodologies to those proposed by CMS in the FY 2007 Proposed Rule for the Inpatient Prospective Payment System (IPPS). This involved first replicating the proposed methodology and then applying alternative methodological choices at various points and comparing how the weights changed. The weights we calculated from our replication of the proposed rule were within 0.5% of the published weights for 90% of the DRGs and for the CS-DRG weights our calculated weights were within 3% for 90% of the CS-DRGs.

This document provides a brief overview of the data sources, methodology, and alternative methodology models. In the following section, we give a brief background to the proposed rule and the aims of this modeling project. Next we provide detail on the methodology we used in calculating weights. First we provide detail on the methods used to replicate the CMS weights. After that we describe technical corrections to how the weights were calculated that we made uniformly for our alternative models, the calculation of the current (FY2006) weights and steps vary in the different alternative models.

II. Background

In the FY 2007 Proposed Rule, CMS proposed the "first significant revision of the inpatient PPS since its implementation in 1983."[1] CMS has proposed a revision of the methodology used to calculate the weights assigned to Diagnosis Related Groups (DRG) for FY 2007 as well as a potential alternative DRG system to be used – an alternative known as "Consolidated Severity-adjusted DRGs" (CS-DRGs) for FY 2008 "or earlier".

The proposed methodology, known as Hospital Specific Relative Value with Cost Centers (HSRVcc) is a departure from the current methodology of charge-based weights. This proposed methodology attempts to account for variations in charges among hospitals through calculation of relative charges. In comparison, the current system uses Indirect Medical Education (IME), Disproportionate Share Hospital (DSH), and wage index adjustments to "standardize" hospital charges.

CMS calculated proposed FY 2007 weights using the FY 2005 MedPAR data and the CS-DRG weights using the FY 2004 data. In order to compare the results of our alternative models, we

[1] CMS, Medicare Proposes Payment and Policy Changes for Acute Care Hospital Services to Inpatients, April 12, 2006, http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1833.

calculated many of the alternatives on both data sets, to eliminate differences due solely to the data year.

In our analysis of alternatives to the proposed methodology we:

- Replicated the proposed methodology and weights for FY 2007,
- Replicated the CS-DRG weights,
- Calculated weights using the "current" FY 2006 weight calculation methodology, and
- Calculated weights using combinations of alternative methodological choices.

In our analyses, we calculated weights using various combinations of methodology, DRG grouper (version 24 and CS-DRG), and data year. We performed a set of technical corrections which we explain in Section IV which we applied uniformly to all of the alternative simulations. The alternative methodology choices that we modeled were:

- Weighting the cost-to-charge ratios for hospital costs and charges,
- Trimming the cost-to-charge ratios at 3.00 standard deviations rather than 1.96, and
- Calculating costs at the claim level by multiplying charges by hospital specific and department specific cost-to-charge ratios.

See table 1 below for an overview of the models and the data and methodology and grouper used for each. Two of these models replicate the CMS weights (Base, rule replication and Base, 2004, CS-DRG). The full list of separate sets of weights modeled by TMC is as follows:

Table 1: Methodology Combinations for Calculation of Weights

Short description	Long description	Year of data used	Methodology system	DRG system
Base, rule replication	Replicate HSRVcc methodology proposed by CMS	2005	HSRVcc	Grouper 24
Base, rule replication with corrections	Replicate HSRVcc methodology proposed by CMS with technical corrections	2005	HSRVcc	Grouper 24
Base but with 2004, with corrections	Take replication logic and apply it to 2004 MedPAR data (Grouper 23) for comparison to the CS-DRG analysis that can only be run on the 2004 data. Include technical corrections.	2004	HSRVcc	Grouper 23
Base, 2004, CS-DRG	Replicate HSRVcc with 2004 MedPAR data, but using CS-DRG.	2004	HSRVcc	CS-DRG
Base, 2004, CS-DRG, with corrections	Replicate HSRVcc with 2004 MedPAR data, but using CS-DRG. Include technical corrections.	2004	HSRVcc	CS-DRG
Base, corrected CCR, weighted	Replicate HSRVcc but adjusting how the cost to charge ratio and the scaling factor is computed. We weight the CCR for volume.	2005	HSRVcc	Grouper 24

Short description	Long description	Year of data used	Methodology system	DRG system
Base, corrected CCR, weighted, and trimming.	Replicate HSRVcc but adjusting how the cost to charge ratio and the scaling factor is computed. We weight the CCR for volume, and trim CCRs at 3.00 standard deviations instead of 1.96.	2005	HSRVcc	Grouper 24
Base, corrected CCR, trimming, not weighted	Replicate HSRVcc but adjusting how the cost to charge ratio and the scaling factor is computed. We trim CCRs at 3.00 standard deviations instead of 1.96.	2005	HSRVcc	Grouper 24
HSRV, departmental level CCRs for costs	Use hospital specific, departmental specific cost to charge ratios that were calculated using 2003 data for the prior project and apply those to the charges at the claim level, then use the HSRV calculation on the costs. This does not use cost centers.	2005	HSRVcc, but departments instead of cost centers.	Grouper 24
Charge based methodology, 2005	Replicate the "current" charge based methodology including standardized charges.	2005	Relative weights -- Existing system	Grouper 24
Charge based methodology, 2004	Replicate the "current" charge based methodology applied to 2004 data, including standardized charges using the CMS grouper 23 DRGs.	2004	Relative weights -- Existing system	Grouper 23
Charge based methodology, CS-DRGs	Replicate the "current" charge based methodology applied to 2004 data, including standardized charges, but using the CS-DRG.	2004	Relative weights -- Existing system	CS-DRG
HSRV without cost centers.	Use HSRV charge based methodology alone (no cost scaler)	2005	HSRV	Grouper 24
Weighted CCRs/HSRVcc/ CS-DRG	This model takes the logic in 3a, but uses weighted CCRs.	2004	HSRVcc	CS-DRG
Weighted and Trimmed CCRs/HSRVcc/ CS-DRGs	This model takes the logic in 3a, but uses weighted and trimmed CCRs	2004	HSRVcc	CS-DRG
Trimmed only/HSRVcc/CS -DRG	This model takes the logic in 3a, but uses trimmed CCRs	2004	HSRVcc	CS-DRG
Weighted CCRs/HSRVcc	This model take the logic in 3a, but uses trimmed CCRs.	2004	HSRVcc	Grouper 23
Weighted and Trimmed CCRs/HSRVcc	This model takes the logic in 3a, but uses trimmed CCRs.	2004	HSRVcc	Grouper 23
Trimmed only/HSRVcc	This model takes the logic in 3a but uses trimmed CCRs.	2004	HSRVcc	Grouper 23

III. CMS Methodology Replication

This section discusses some of the technical details on how we replicated the CMS weights. In order to completely replicate the weight calculation a very high level of detail is needed. In just a few areas CMS did not include sufficient detail in the proposed rule. We are very grateful to CMS staff who clarified many fine points of detail.

CMS used two sources of data for calculation of weights, hospital inpatient claims and hospital cost reports. We used the same sources. They are:

- *Hospital Inpatient Claims* - Data from the FY2004 MedPAR and the FY2005 MedPAR files were used. CS-DRGs existed only on the FY2004 MedPAR data so all analyses conducted with CS-DRGs were with that data.

- *Hospital Cost Report Data* - Hospital Cost report data were from the Hospital Cost Report Information System (HCRIS), from their data release of December 31, 2005.

We describe below five steps to calculating the HSRVcc weights:

- Data cleaning,
- Calculating CCRs,
- Calculating hospital specific relative value (HSRV) weights using charges,
- Creation and application of the scalers, and
- Normalizing the weights.

A. Data cleaning

In the Proposed Rule, CMS used slightly different data cleaning approaches for their analyses that were conducted with 2004 data versus the analyses conducted with 2005 data. The data cleaning steps for the 2004 data are more comparable to the MedPAC analysis. This discussion will focus on the 2005 data cleaning since we used that in most of our models. There will be a brief section highlighting some of the differences on the 2004 analysis.

1. Cleaning of Hospital Inpatient Claims

We followed what CMS described starting at P. 184 of the display copy of the Proposed Rule. These are the steps in cleaning the data file that CMS applied to the FY 2005 data for calculation of the proposed FY 2007 weights. CMS used slightly different cleaning rules for the FY 2004 data with the CS-DRG weights. To be able to compare between the replication and alternative policy models, we used the data cleaning that CMS applied to the FY 2005 data to all of our simulation models even those using the FY 2004 data, with the exception of the one model in which we are replicating the CS-DRG weights to compare to the published weights (Base, 2004, CS-DRG).

We excluded discharges that:

- Were not from PPS hospitals – third digit of provider code was not equal to 0 or special unit characteristic code was not blank.
- Had total charges equal to 0.
- Had length of stay equal to 0.
- Had an "ungroupable" DRG assignment: DRG 470 in Grouper versions 23 or 24, CS-DRG 999. Note: This exclusion is not explicitly in the rule, but verified with CMS during a phone call.
- Were for Medicare Beneficiaries enrolled in a Medicare+Choice (Medicare Advantage) plan.
- Had total charges that differed by more than $10 from the sum of the component charges.
- Were from hospitals that were Critical Access Hospitals (CAH) or later became CAHs. The list of CAHs was downloaded from the CMS website. (http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending&itemID=CMS063084, which as of 6/2/06 has a note saying that the list will be updated in the Final Rule).
- Were for heart and heart-lung, liver and/or intestinal, or lung transplants (DRGs 103, 480, and 495) performed at hospitals not approved by Medicare for transplants.
- Were at providers not included on the provider specific file list provided by CMS. (http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending&itemID=CMS061281). As a by-product of this restriction, Cancer and Indian Health Service hospitals were removed.
- Were at providers where there were no charges in at least 8 of the 10 cost centers.
- Had total charges and total charges per day greater than three (3) standard deviations from their respective geometric means.[2]

[2] We verified that CMS used the logical "and" in applying this outlier exclusion criteria. That is, if an observation meets on only one condition, total charges or charges per day are outliers, the record is retained for calculating weights.

The following are the major differences between the cleaning steps used with the 2005 and the steps CMS used with the 2004 data for the CS-DRG replication.

- In 2004, hospitals from Maryland were excluded, but they were included in 2005.
- Providers were excluded if they did not have charges in the two accommodation cost centers and at least one ancillary cost center. This is in contrast to requiring 8 cost centers in the 2005 analysis.

When preparing the data, we did the following:

- We assumed that professional fees – MedPAR Service Charge category 22 should be counted under "Other". We verified this assignment during a phone call with CMS.
- Transfer DRGs identification.
    - For Grouper 23 and 24, we followed the identification of whether or not a DRG was considered a transfer DRG as reported by CMS.
    - For CS-DRGs, we determined what could be a transfer DRG based on logic published on August 12, 2005 in the Federal Register on P. 47484. The language reads:

> "(A) The total number of discharges to post acute care in the DRG must equal or exceed the 55th percentile for all DRGs;
> (B) The proportion of short-stay discharges to post acute care to total discharges in the DRG exceeds the 55th percentile for all DRGs; and
> (C) The DRG is paired with a DRG based on the presence or absence of a comorbidity or a complication or major cardiovascular condition that meets the criteria specified under paragraph (d)(3)(ii)(A) and (d)(3)(ii)(B) of this section."

2. Cleaning of Hospital Cost Report data

For cleaning of the hospital cost report data, we followed the logic starting on P. 190 of the display copy of the Proposed Rule.

We removed hospitals if they met any of the following criteria:

- Critical access hospitals (CAHs)
- Located in Maryland
- Indian Health Service
- Cancer hospitals
- All-inclusive rate hospitals. Based on guidance from CMS during a phone call, these were identified by having a "Y" in cost report location S2_1_32.
- Was not a full year (365 days) cost report.
- Cost report did not start during Federal FY2003 (October 1, 2002 through September 30, 2003).

We discovered that the calculation of CCRs is very sensitive to which hospitals are included or excluded. Using the same list of CAHs is particularly important.

All cost reports are used whether or not the cost report is settled or merely submitted. The cleaning of the cost report data and the cleaning of the MedPAR data are independent of each other. Hospitals can be excluded from the cost report file for not having a full year cost report or an available cost report for FY 2003, but claims from these hospitals would be kept in the MedPAR claims.

B. Calculate CCRs

We created 10 cost centers based on the mapping starting on P. 186 of the display copy of the Proposed Rule. CMS used an internal file in a different format, though derived, from the file that is publicly available. When we attempted to match the scalers CMS posted on the web site, our results came closest if we did not include the sublines in the cardiology cost center. Our replication of the scalers was within 0.5% for all of the cost centers except cardiology, other services and laboratory, with cardiology being the furthest away from the CMS released number. For cardiology when we included appropriate sublines we were 7.4% lower than CMS's number. When we excluded the sublines, we were 2.1% lower than CMS's number.

We trim the individual cost center cost to charge ratio (CCR) to remove outliers. An individual cost center CCR is not used in calculations if one of the following is true:

- CCR is greater than 10.
- CCR is less than 0.01.
- CCR is more than 1.96*standard deviations different from the geometric mean.

The trimming of the CCRs is done in this order so that the geometric mean is computed after the cost center CCRs with the unreasonable values were removed from the calculations.

When trimming, we only removed the CCR for that individual cost center, the other CCRs for that provider are still present. Therefore, slightly different pools of hospitals are used for every calculation of cost center CCRs.

After the trimming, we compute the geometric mean of the CCR for every cost center. CMS computed an unweighted geometric mean.

C. Calculating hospital specific relative value (HSRV) weights using charges

In order to replicate the methodology for HSRVcc, we followed the basic logic laid out starting on P. 186 of the display copy of the Proposed Rule. This methodology is applied at the cost center level.

The basic logic of the HSRVcc is summarized as follows:

1. Calculate each hospital's average charge per discharge for all discharges for each of the 10 cost center groupings. This is calculated as the sum of the charges divided by the transfer adjusted case count.

2. Calculate the relative charge per discharge for each of the 10 cost center groupings. Divide the total charges for each individual discharge by the average charge per discharge for all that hospital's discharges (from step 1).

3. Initialize the Case Mix Index (CMI) as 1.0.

4. Calculate the CMI adjusted relative charge. Multiply the relative charge per discharge (from step 2) by CMI (from step 3).

5. Calculate the mean CMI adjusted relative charge for each DRG, for each cost center grouping. This is calculated as the sum of the CMI relative adjusted relative charge (from step 4) divided by the sum of the transfer adjusted case count (from step 4) for each DRG.

6. Calculate the mean CMI adjusted relative charge at the national level. This is calculated as the sum of the CMI adjusted relative charge (from step 4) divided by the sum of the transfer adjusted case count (from step 4) at the national level.

7. Calculate the first set of weights. Divide the mean CMI adjusted relative charge at the DRG level for each cost center grouping (step 5) by the mean CMI adjusted relative charge at the national level (step 6). This is computed for each DRG.

8. Assign these weights to all the cases for each hospital.

9. Calculate each hospital's case mix index (CMI) using these new weights (Step 8).

10. Calculate a new CMI adjusted relative charge. This is computed by multiplying the relative charges by the new computed CMI.

11. Calculate a new mean CMI adjusted relative charge at the DRG level.

12. Calculate a new mean CMI adjusted relative charge at the national level.

13. Calculate a new weight by dividing the results of step 11 by step 12.

14. Repeat back to step 8 until the maximum change in national case mix index from the current iteration compared to the previous iteration is less than 0.000001.

15. At this step, we have 10 weights (one for each cost center) for every DRG.

D. Creation and application of the scalers

16. Using the national average CCR for each cost center, multiply the total unadjusted charges for that cost center by the national average CCR for that cost center to compute a "cost" for that cost center.

17. Sum the 10 cost center costs (computed in step 16) to create a single "total cost" for the discharge.

18. For each cost center, divide the "cost for the cost center" (step 16) by the "total cost" (step 2). The result is a "scaling factor" for each cost center.

19. Apply the scaling factor for each cost center (step 18) to the cost center weights for each DRG.

20. Sum the results of step 19, to create a single weight for each DRG.

E. Normalizing the weights

21. Apply the normalization factor to the weights by multiplying the weight (step 20) by the normalization factor. We used the normalization factor published in the Proposed Rule.

22. For low-volume DRGs (DRGs with less than 10 cases), on models using Grouper 23 or 24, we replaced weights following the mapping starting on P. 192 of the display copy of the Proposed Rule. For models using CS-DRGs, we did not make any adjustments.

IV. Corrections from the CMS Methodology

There were a few "corrections" made to our model from the replication to our corrected models. These were either mistakes that had been made by CMS or inconsistencies between the treatment of 2004 data and 2005 data that we wished to be consistent in our modeling. Below we list those corrections applied to all of our alternative models.

- *Organ acquisition costs in 2005.* In our replication, we discovered that organ acquisition costs appeared to have been incorrectly included in the total charges. We verified this with CMS. CMS noted that they will make this correction in the final rule. We do not believe that they made this mistake when using the 2004 data.

- *Transfer adjustment.* When replicating the 2005 results, we used transfer adjusted weights. However, when attempting to replicate the 2004 results with CS-DRGs, our results were closest when we did not use transfer adjustments. We believe though that there should be transfer adjustment when using CS-DRGs and so in our corrections, that is done.

- *Differences between CMS's analysis using 2004 and 2005 data.* There are several differences between CMS's analysis using 2004 data and their analysis using 2005 data. The major differences are:
    - Exclusion in 2004/Inclusion in 2005 of discharges from Maryland hospitals. In the 2004 analysis, CMS excluded the Maryland hospitals but they included them in 2005. As noted above, this was intentional in order to have CS-DRG weights that used the 2004 data more comparable to MedPAC's analysis. Because we wanted consistency between our models in general in our "corrected" models, we followed 2005.
    - Cleaning of MedPAR file based on cost centers. In 2004, CMS required charges in the two accommodation cost centers as well as one ancillary cost center. In contrast, in 2005, CMS required presence of data in at least 8 cost centers. For our general "corrected" models, we followed the 2005 approach.
    - Use of transfer adjusted case counts versus non-transfer adjusted cases while computing Case Mix Index (CMI) during the iterations. CMS used transfer adjusted counts of cases to calculate the CMI used during the HSRV weight calculation iterations in the 2004 data used for CS-DRG weights. In the proposed FY 2007 weight calculation (HSRVcc DRG) using 2005 data, CMS calculated the CMI without adjusting for transfer cases. For our corrected models, we followed the logic for the FY 2007 proposed weights. (See P. 190 of the display copy of the Proposed Rule for details.)

V. Overview of Current Methodology Replication

In this section we provide a summary of how CMS calculated the DRG weights in 2006 – the "current methodology". We used these steps to calculate what the weights would have been using the 2005 and 2004 data (Charge based methodology, 2005 and Charge based methodology, 2004) to be able to compare what effect the change in the calculations had on the weights separate from the changes due to using a different dataset.

Total charges for each discharge are adjusted by the hospital's wage index, IME, DSH, and COLA factors according to the following formula:

Operating portion

(a) std_labor_operating=((total_charges*labor_share)/wage_index)

(b) standardized_operating=std_labor_operating
/(1+ime_adjustment_operating+dsh_adjustment_operating)

Capital portion

(c) std_labor_capital=((total_charges*(1-labor_share))/cola_adjustment)

(d) standardized_capital=std_labor_capital
/(1+ime_adjustment_capital+dsh_adjustment_capital)

Combined – final standardized charge

(e) standardized_charge=standardized_operating
+ standardized_capital

The weights are then calculated using these standardized charges using the following steps:

1. Calculate mean for each DRG of the standardized charges.
2. Calculate mean standardized charge of all discharges.
3. Divide the mean standardized charges for the DRG by the mean of all discharges.
4. Multiply each weight by the normalization factor. We used the normalization factor published in the Proposed Rule.

VI. Methodology Variations

For our different models, we adjusted certain aspects of the cleaning and methodology. The list here presents variations. Our models are combinations of these changes, the CMS methodology, different years of data and different DRG groupers.

Inpatient claims cleaning – organ acquisition cost correction

Applies to:	All 2005 Models except Base, rule replication
Change:	CMS incorrectly included the organ acquisition costs with 2005 data. This change removed the charges related to organ acquisition.

Inpatient claims cleaning – cost centers

Applies to:	Base, 2004, CS-DRG, with corrections
Change:	We removed providers who did not have information in at least 8 of the 10 cost centers, following how CMS analyzed the FY2005 data. This is in contrast to their analysis of 2004 data where they removed providers if the provider did not have charges in: routine days, intensive days, and at least one other cost center.

Weighted CCRs

Applies to:	Base, corrected, CCR, weighted; Weighted CCRs/HSRVcc; Weighted CCRs/CS-DRGs.
Change:	We computed a weighted national CCR as opposed to a geometric mean CCR.

Weighted and trimmed CCRs

Applies to:	Base, corrected CCR, weighted and trimmed; Weighted and trimmed CCRs/HSRVcc/CS-DRGs; Weighted and trimmed CCRs/HSRVcc.
Change:	We computed a weighted national CCR as opposed to a geometric mean CCR. In addition, we trimmed outliers that were at least 3.00*standard deviation away from geometric mean as opposed to 1.96*standard deviation away from the geometric mean.

Trimmed CCRs

Applies to:	Base corrected CCR, trimming, not weighted; Trimmed only/HSRVcc; Trimmed only/HSRVcc/CS-DRGs
Change:	We trimmed outliers that were at least 3.00*standard deviation away from geometric mean as opposed to 1.96*standard deviation away from the geometric mean.

Single cost center

Applies to:	HSRV without cost centers
Change:	This model uses a single cost center as opposed to the 10 cost centers.

Costs

Applies to:	HSRV, departmental level CCRs for costs
Change:	This model uses total costs as opposed to the 10 cost centers using charges. Total costs are calculated at the claim level by multiplying the charges for each of the 30 costs centers in MedPAR by the relevant

departmental CCR for that hospital and summing the costs across the 30 cost centers.

CMS DRGs V. 23 and HSRVcc

Applies to:	Base, but with 2004, with corrections
Change:	This model followed P. 65 of the display copy using the transfer adjusted case mix as opposed to the non-transfer adjusted case mix.

EXHIBIT C

EXHIBIT C

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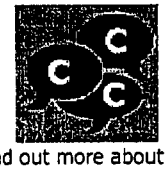

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Transitions and Transformations

6/2/2006 11:43:00 AM

By Grace-Marie Turner

Roy Ramthun, our friend, valued colleague, and leader in the free-market health reform movement, is leaving the administration today after three years of service at the White House and at Treasury.

Roy has been an architect of visionary health care proposals that will usher the consumer-directed health care movement into the next era, and he oversaw the speedy development of the guidelines for Health Savings Accounts.

We are sorry to see him go after three years of round-the-clock service, but we know that he will continue to lend his skills and expertise to the cause in his next venue.

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One of the things that Roy worked hardest to promote was price transparency - a crucial tool for consumers in the new health care economy. And yesterday, that movement toward price transparency got a big boost: The Centers for Medicare and Medicaid Services posted a gigantic spreadsheet on what Medicare paid last year for 30 elective inpatient hospital procedures and other common hospital admissions.

The spreadsheet offers information for each state, each county in every state, and each hospital in every county for a variety of treatments they provided in 2005, including heart operations, hip and knee replacements, kidney and urinary tract operations, gallbladder surgery, and back and neck operations.

One of the first things you notice is the huge discrepancy between the national averages of what the hospitals charge and what Medicare actually pays. Medicare's payment is generally a third or less of the hospital charges. For example, Medicare's average payment, nationally, for a heart valve operation is $38,538, but the average hospital list price is $115,221.

There also are big price differentials when you drill down into the data. CMS lists the ranges of Medicare payments by county, but hospital-specific pricing data is not yet available. You see that the valve replacement could cost as little as $26,600 in Schenectady, NY, but more than $68,000 in Hardin County, KY.

CMS does list the number of procedures for each hospital - which is a good indicator of the hospital's expertise and consequently of more successful outcomes. From the data Medicare has published, you may be better off at Florida Hospital in Orange County with 177 heart valve replacements last year rather than Salina Regional Health Center in Kansas, with only 11.

And this is just phase one: CMS will post payment information for ambulatory surgery centers later this summer, and for common hospital outpatient and physician services this fall.

Kudos to CMS Administrator Mark B. McClellan, M.D., Ph.D. and his team at CMS for this heroic effort.

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EXHIBIT D

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May 10, 2006

MODELING FFY 2007 OUTLIER PAYMENTS

DATA SOURCES.

1. The MEDPAR 2005 computer file obtained from CMS. The file contains 13,715,186 records, each corresponding to a Medicare hospital discharge occurring in FFY 2005.

2. CMS FFY 2007 Impact File (Proposed Rule Version). This file produced by CMS shows the estimated level of FFY 2007 outlier payments by hospital (as percentages). It also shows the hospital-specific parameters used for calculating PPS payments, such as DSH and IME adjustment factors, cost to charge ratios (CCRs), wage indexes, etc.

3. The March 31, 2006 update of the HCRIS database. This database consists of Medicare cost reports beginning in Federal Fiscal Years (FFYs) 1996 through 2005.

REPLICATION OF THE CMS ESTIMATED 2007 OUTLIER PAYMENT LEVELS (IPPS 2007 PROPOSED RULE).

The regular and outlier FFY 2007 payments were estimated for 11,447,430 discharges in the MEDPAR database subject to IPPS. These are the same discharges used by CMS to generate the 2007 Proposed Rule Impact File[1]. Regular payments were calculated based on the proposed DRG weight, the patient discharge destination (for identifying transfers), the applicable proposed standardized amounts and the other hospital-specific parameters determining PPS payments. The latter are the wage index, the non-labor cost of living adjustment, and the DSH and IME adjustment factors. Each of these parameters has different values applicable to operating and capital payments. The parameters were obtained from the CMS Impact File.

Outlier payments were calculated inflating 2005 charges by 15.71 percent (the inflation factor used by CMS[2]), reducing charges to costs using the cost to charge ratios from the CMS Impact File and comparing costs to the proposed FFY 2007 fixed loss amount of $25,530. The latter was adjusted as appropriate on a hospital-specific basis. It should be noted that the Impact File cost to charge ratios are mostly from fiscal periods beginning in FFY 2004. Also, no allowance was made for the anticipated continued decrease in the CCRs.

With these assumptions, the FFY 2007 operating and capital outlier payments were estimated at 5.1 and 4.81 percent of the respective total payments, net of DSH and IME amounts. These estimates are in good agreement with the CMS figures of 5.1 and 4.87 percent, respectively. The dollar amount of FFY 2007 outlier payments was estimated at $4,774B.

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1 These are discharges subject to IPPS and with non-zero covered days and charges. The number of these discharges is the same as the number of "Bills" for all the hospitals in the Impact File.

2 The two-year inflation factor in the Proposed Rule is stated to be 15.15 percent. This is not consistent with the annual inflation ratio of 7.57 percent stated in the same Proposed Rule. The annual inflation rate of 7.57 percent translates into a 15.71 percent two-year rate.

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT USING THE MOST RECENT COST TO CHARGE RATIOS.

More recent cost to charge ratios were calculated from the latest cost reports available in the HCRIS database. Medicare inpatient operating costs were obtained from Worksheet D-1, Part II, Medicare inpatient capital costs from Worksheet D, Parts I and II and Medicare inpatient charges from Worksheet D-4. A comparison with the dates of the CCRs in the Impact File, presumably used to establish the proposed FFY 2007 fixed loss threshold, is shown in the table below.

Beginning in FFY	Number of Cost Reports Used for the Impact File CCRs	Percent of Cost Reports Used for the Impact File CCRs	Number of HCRIS Most Recent Cost Reports for Impact File Hospitals	Percent of HCRIS Most Recent Cost Reports for Impact File Hospitals
	(a)	(b)	(c)	(d)
2001	5	0.2%	3	0.1%
2002	39	1.4%	13	0.4%
2003	739	27.0%	92	2.6%
2004	1,949	71.1%	2,948	84.0%
2005	10	0.4%	453	12.9%
Unknown/Not Matching	780		13	
Total	3,522		3,522	

Table Notes: Column (a) numbers are based on matching Impact File CCRs with HCRIS CCRs for fiscal periods beginning between 2001 and 2005. If both operating and capital HCRIS CCRs were within 0.001 of their respective Impact File counterparts, the HCRIS cost report was considered to be the source for the Impact File CCRs. Percentages in columns (b) and (d) are based on the total of FFYs 2001-2005, i.e., unkown/not matching hospitals were not included.

Using the more recent HCRIS CCRs and the CMS assumptions listed above, the estimate of the fixed loss threshold is **$24,990**.

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT PROJECTING BOTH CHARGE AND COST INFLATION.

Outlier payments are calculated from costs. Costs are determined by applying a cost to charge ratio to actual charges. It follows that accurate outlier estimates require projecting **both** costs and charges.

An additional complication is the inevitable lag between CCRs that can only be determined retrospectively at the end of an elapsed cost reporting period and the current charges to which they are applied. Historically, CMS has projected outlier payments by projecting only costs or only charges and ignored the time lag problem. This approach works well in periods when cost and charges move more or less in tandem. When costs and charges change at significantly different rates, relying on only one measure of inflation can result in either outlier over- or underpayments[3]. An alternative methodology that overcomes these shortcomings is described below.

In order to account for the time lag problem, cost to charge ratios were projected from the most recent fiscal period in the March 31, 2006 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining FFY 2007 outlier payments. The CMS Program Memorandum A-03-058 dated July 3, 2003 instructs Fiscal Intermediaries to update the CCRs "not later than 45 days after the date of the tentative settlement or final settlement used in calculating the CCRs". Combining this deadline with the maximum of eight months between the end of the cost reporting period and tentative settlement, it is reasonable to expect CCRs to be updated no later than nine months after the end of the cost reporting periods. Assuming a nine-month lag in updating CCRs, FFY 2007 outlier payments will be based partly on 2005 and partly on 2006 ratios, depending on the fiscal period ending date (FPE). Hospitals with a January FPE will have their CCR updated to the FPE January 2006 value by October 31, 2006. Their FFY 2007 outlier payments will be based on the FPE January 2005 CCR for one month (October 2006) and on the FPE January 2006 CCR for the remaining eleven months. Similarly, FFY 2007 outlier payments for hospitals with a February FPE will be based on the 2005 CCR for two months and the 2006 CCR for ten months, and so on. Hospitals with a December FPE would have their FFY 2007 outlier payments based entirely on the FPE December 2005 CCR.

The cost inflation factor for projecting CCRs was determined from the costs reports of a cohort of 3,253 matched hospitals for periods beginning in FFYs 2002, 2003 and 2004. All three costs reports were available for each hospital from the recent update of HCRIS and covered a full twelve months. The 2002-2004 aggregate annual rate of increase in the cost per discharge for these hospitals was 5.69 percent[4]. This cost inflation factor and the CMS charge inflation factor of 7.57 percent were used to project cost to charge ratios over the time periods described above. The projected CCRs were applied to projected FFY 2007 charges to simulate the determination of costs for FFY 2007 outlier payments. The estimated fixed loss amount that would result in 5.1 percent outlier payments in this scenario is **$24,000**. It should be noted that this model (as well as all the ones discussed here) does not take into account the potential impact of outlier reconciliation. The model assumes FFY 2007 outlier payments based on costs determined using pre-2007 CCRs. If outlier payments were adjusted retrospectively based on FFY 2007 "true" costs determined using 2007 CCRs, final outlier payments would be lower (assuming a continuing trend of decreasing cost to charge ratios).

---

3 Of course, regardless of methodology, over- or under estimates of outlier payments may result from cost and/or charge inflation projections -usually based on the assumption that historical values are a reasonable indicator of future trends- that turn out to be inaccurate.

4 An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 2,791 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2006 HCRIS update.

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT PROJECTING ONLY COST INFLATION.

This is the methodology CMS used for the FFYs 1994-2002. For projecting FFY 2007 outlier payments it consists of applying historical CCRs to FFY 2005 charges to determine FFY 2005 costs. These costs are projected forward to FFY 2007 using a cost inflation factor. However, the "cost inflation only" approach ignores the time lag problem. This may result in underestimating FFY 2007 costs for outlier payment determination and, therefore, underestimating the FFY 2007 fixed loss threshold. The underestimate results from using historical CCRs generally more recent than the CCRs actually available in 2004[5].

The cost inflation approach using an annual cost inflation factor of 5.69 percent and the Impact File CCRs resulted in a FFY 2007 estimated fixed loss amount of **$23,055**. If the most recent CCRs from the HCRIS database were used instead, the estimated FFY 2007 fixed loss amount was **$22,645**.

ESTIMATE OF THE FFY 2006 OUTLIER PAYMENTS

The 2007 IPPS Proposed Rule states that FFY 2006 outlier payments are now estimated at 4.71 percent of total DRG payments. Using the "charge inflation only" model and the Impact File cost to charge ratios, the outlier payment level was estimated at 4.64 percent, essentially replicating the CMS finding. Using the same model, the 2006 fixed loss amount that would result in a payment level of 5.1 percent was estimated at **$21,530**.

The FFY 2006 fixed loss amount was estimated using all the other models described above. Still using the "charge inflation only" but substituting the most recent HCRIS CCRs for the Impact File ratios, the fixed loss threshold was estimated at **$21,160**. It should be noted that the most recent CCRs used in these model were selected by taking into account their applicability to FFY 2006. For example, assuming a nine-month lag in updating CCRs, hospitals with fiscal periods ending in June 2006 had their first six months of FFY 2006 outlier payments based on the June 2004 FPE cost to charge ratio, and the last six months based on the June 2005 FPE ratio. Even if the June 2005 FPE ratio was available from the HCRIS database, the CCR used in this model was an average of the 2004 and 2005 ratios weighted by the number of months of usage in FFY 2006.

If both cost and charge inflation are taken into account, and assuming a nine-month lag in updating CCRs, the FFY 2006 fixed loss threshold amount was estimated at **$21,275**.

Using the "cost inflation only" models the fixed loss amounts were estimated at **$20,460** and **$20,095**, based on Impact File and most recent HCRIS cost to charge ratios, respectively. Because of

5 This discussion assumes charges increasing at a faster pace than costs. In that case, because FFY 2007 "costs for outlier payment determination" are obtained by applying CCRs from earlier periods to FFY 2007 charges, 2005 "costs" should be determined with similarly lagged CCRs.

the problems with the "cost inflation only" model noted for the FFY 2007 estimates, i.e. not taking into account the lag in updating CCRs, it is quite likely these amounts are underestimated.

Both FFY 2006 and 2007 results and underlying assumptions are summarized in the tables on the following pages.

CALCULATION OF THE FFY 2005 FIXED LOSS AMOUNT THAT WOULD HAVE RESULTED IN OUTLIER PAYMENTS OF 5.1 PERCENT

The level of outlier payments actually made in 2005 can be determined from the 2005 MEDPAR data. The operating outlier payment, if any, is explicitly shown for each Medicare discharge. The regular DRG operating payment can be easily determined from data in the file. Specifically, the operating payment net of indirect medical and disproportionate share adjustments is the DRG PRICE less CAPITAL, DSH and IME payments. The amounts shown in capitals are all fields in the MEDPAR records. The total outlier payments made in 2005 amounted to 3.051B[6]. This represents 3.8 percent of total Medicare IPPS payments net of indirect medical and disproportionate share adjustments. The result is significantly different from the CMS estimate of 4.1 percent. The 3.8 percent level of outlier payment translates into a shortfall of $1.1B.

The outlier amounts that should have been paid could be calculated from the MEDPAR data if the cost to charge ratios actually used were available. To my knowledge there is no public data source for them. An alternative would be to estimate the CCRs from other data sources, e.g., HCRIS. However, this would involve assumptions about the rates of cost and charge inflation. In order to avoid dependence on such assumptions the CCRs were estimated from the MEDPAR file itself. The comparison of any two outlier payments *calculated using the same CCRs* allows the determination of the CCR:

$O_1 = 0.8 \times (OPCCR \times C_1 - D_1 - AFL)$

$O_2 = 0.8 \times (OPCCR \times C_2 - D_2 - AFL)$

where O = outlier payment, C = charges, D = DRG payment, AFL = adjusted fixed loss amount and OPCCR = operating cost to charge ratio.

Note that AFL is actually dependent of the cost to charge ratios, but since it cancels out of the final equation, this fact can be ignored

Subtracting the second equation from the first and solving for OPCCR:

$$OPCCR = [(O_2 - O_1) / 0.8 + (D_2 - D_1)] / (C_2 - C_1)$$

A similar calculation can be carried out for the capital cost to charge ratio. This method was used to determine the CCRs by arraying all outlier payments made to a hospital during a given quarter in

6 The aggregated amount of outlier payments for the 11,447,430 discharges in the 2005 MEDPAR selected as described on Page 1.

increasing order of the covered charges. The calculation shown above was performed by comparing each outlier payment in the array to the outlier payment with the highest covered charges and, again, to the outlier payment with the lowest charges. The median of the CCRs thus obtained was considered to have been the CCR used to determine outlier payments for the quarter and hospital under consideration. If the actual CCR remained the same during the entire quarter, the method above should in principle determine it exactly. If the CCR did change during the quarter, the calculation yields an approximate "effective" CCR. (The date of discharge shown in the public version of MEDPAR is limited to the quarter of discharge). The approach outlined above can be applied only when a hospital had at least two outliers in a given quarter. For hospitals with less than two outliers in a quarter, the CCR ratios were taken from the CMS Impact File for FFY 2005 (the Final Rule version).

In order to validate the CCRs obtained as described above, they were used to calculate "simulated" 2005 outlier payments based on the fixed loss amount of $25,800 effective in FFY 2005. The total amount of "simulated" payments was $3,036B compared with the actual amount of $3,051B[7]. The CCRs were then used to calculate the 2005 fixed loss amount that would have resulted in a 5.1 percent outlier payment level. The result was **$19,790**.

7 The comparison was limited to cases when outlier payments were actually made. Simulated payments for all cases are slightly higher ($3,132B). This may reflect situations when outlier payments were denied for not being submitted in accordance with Medicare laws and regulations.

FFY 2007 ESTIMATED FIXED LOSS AMOUNTS AND UNDERLYING ASSUMPTIONS

METHODOLOGY	Data Source for Cost to Charge Ratios	Charge Inflation (Proposed Rule, Rate of Change from Jul-Dec 2004 to Jul-Dec 2005) (Per Year)	Cost Inflation (Per Year)	Change in Cost to Charge Ratios (Per Year)	Assumed Lag Between the Fiscal Period End and Effective Date of the CCRs	ESTIMATED FFY 2007 FIXED LOSS AMOUNT ($)
Charges Projected From FFY 2005 to FFY 2007	CMS Impact File-Proposed FY 2007	7.57%	None	None	None	25,530
Charges Projected From FFY 2005 to FFY 2007	HCRIS 03/31/2006 Update	7.57%	None	None	None	24,990
Charges Projected From FFY 2005 to FFY 2007; Cost to Charge Ratios Projected to Simulate Effective CCRs for FFY 2007 Outlier Payments	HCRIS 03/31/2006 Update	7.57%	5.69% (From HCRIS Cost Reports 2002-2004)	-1.75%	Nine Months	24,000
Costs Projected From FFY 2005 to FFY 2007	CMS Impact File-Proposed FY 2007	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	23,055
Costs Projected From FFY 2005 to FFY 2007	HCRIS 03/31/2006 Update	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	22,645

FFY 2006 ESTIMATED FIXED LOSS AMOUNTS AND UNDERLYING ASSUMPTIONS

METHODOLOGY	Data Source for Cost to Charge Ratios	Charge Inflation (Proposed Rule, Rate of Change from Jul-Dec 2004 to Jul-Dec 2005) (Per Year)	Cost Inflation (Per Year)	Change in Cost to Charge Ratios (Per Year)	Assumed Lag Between the Fiscal Period End and Effective Date of the CCRs	ESTIMATED FFY 2006 FIXED LOSS AMOUNT ($)
Charges Projected From FFY 2005 to FFY 2006	CMS Impact File-Proposed FY 2007	7.57%	None	None	None	21,530
Charges Projected From FFY 2005 to FFY 2006	HCRIS 03/31/2006 Update	7.57%	None	None	None	21,160
Charges Projected From FFY 2005 to FFY 2006; Cost to Charge Ratios Projected to Simulate Effective CCRs for FFY 2006 Outlier Payments	HCRIS 03/31/2006 Update	7.57%	5.69% (From HCRIS Cost Reports 2002-2004)	-1.91%	Nine Months	21,275
Costs Projected From FFY 2005 to FFY 2006	CMS Impact File-Proposed FY 2007	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	20,460
Costs Projected From FFY 2005 to FFY 2006	HCRIS 03/31/2006 Update	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	20,095

EXHIBIT E

VAIDA HEALTH DATA CONSULTANTS
3209 Curlew Street Davis, California 95616-7517 (530) 758-0493
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June 6, 2006

ESTIMATE OF THE FFY 2005 FIXED LOSS AMOUNT PROJECTING BOTH CHARGE AND COST INFLATION (FINAL 2005 IPPS RULE CHARGE INFLATION ESTIMATE)

My July 8, 2004 report issued in conjunction with the Proposed IPPS 2005 Rule describes an outlier projection methodology that takes into account both cost and charge inflation, as well as the time lag between retrospectively determined cost-to-charge ratios (CCRs) and current charges to which they are applied. The annual charge inflation factor used under that methodology was 14.5083 percent as estimated by CMS in the Proposed IPPS 2005 Rule. The annual cost inflation factor was 7.17 percent, the historical annual rate of increase between 2000 and 2002 as determined from Medicare cost reports. The 2005 fixed loss amount that would have resulted in 5.1 percent outlier payments under these assumptions was estimated at **$28,445**.

In the Final IPPS 2005 Rule CMS reduced the annual charge inflation estimate from 14.5083 to 8.9772 percent resulting in a reduction of the 2005 fixed-loss amount from the proposed $35,085 to the final value of $25,800. I now reproduced the 2005 fixed-loss amount calculation described above with one change: the annual charge inflation factor was reduced from 14.5083 percent, as set forth in the Proposed Rule, to 8.9772 percent, as set forth in the Final 2005 Rule. The resulting estimate of the 2005 fixed-loss amount under the cost and charge inflation methodology is **$24,200**. Please note this estimate was generated with the data available at the time of the Proposed IPPS 2005 Rule.

154

Monongalia Health System

May 30, 2006

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

On April 12, 2006 the Centers for Medicare and Medicaid Services released its Notice of Proposed Rule Making for FY2007 changes to Medicare's hospital inpatient prospective payment system. These proposed changes are scheduled to take effect on October 1, 2006. As President and Chief Executive Officer of Monongalia General Hospital in Morgantown, West Virginia, I am writing to you to discuss my very serious concerns about the impact that these changes will have on Monongalia General Hospital, and other community hospitals performing large volumes of procedures involving cardiac and orthopedic implanted devices.

It is my understanding that some of the basis for the proposed changes stem from the desire to more accurately align the payment of inpatient hospital services to the costs of providing the services and to limit the ability of for-profit limited service hospitals to select services and patients based on profitability considerations. I strongly endorse and support the need to correct this major failing of the existing system. However, Monongalia General Hospital (MGH) is an example of an institution that is unintentionally adversely impacted by these changes. MGH is a not-for-profit community hospital serving the needs of the citizens of Monongalia, Marion, and Preston counties in West Virginia. Despite the fact that MGH is located in the same community as West Virginia University Hospital, MGH is the market leader in terms of orthopedic and interventional cardiac care for the communities that we serve. Over the years, MGH has developed an extraordinarily strong reputation in these service areas, and we accept all patients who present to us regardless of their ability to pay. However, interventional cardiology and orthopedics represent a significant portion of our total revenues, and as a result, while we are a relatively small hospital (average daily census of 105 patients) we are the 51st most heavily impacted hospital in the nation by these proposed changes, resulting in a reduction of $2.2 million annually in our reimbursement.

Monongalia General Hospital was originally constructed in 1977, and in the last 30 years very little has been done to our physical facilities. We are in significant need of expansion and modernization, and as a result, MGH has just initiated a $97 million modernization project. Without considering the impact of these proposed changes, MGH

is budgeted for an operating margin of $1.3 million for the fiscal year ending June 30, 2007. The reduction in reimbursement that the proposal to a cost-based DRG payment system will have on our facility will be nearly double our entire operating margin, and

this is before principal payments on $70 million of bonds will begin to take effect. In addition to the negative impact of the cost-based DRG system, we understand that the annual impact of the changes to the proposed severity adjusted DRG system will reduce our payments from Medicare by an additional $2.7 million per year. Clearly, these proposed changes have a very grave impact on MGH.

West Virginia is a rate regulated state, and therefore, MGH has no ability to recapture these reimbursement reductions through charges to other payers. At the present time, MGH is reimbursed 80.4% of our actual costs of providing care to Medicare patients, and this will significantly reduce this already alarmingly low figure. I would strongly encourage you to exempt community, not-for-profit hospitals from these reimbursement reductions as this is not the group of hospitals that were the intended target of these changes and there severe flaws in the proposed reimbursement system. In the case of MGH, without some regulatory relief, these changes will be devastating.

I would also like to point out a fundamental flaw which I believe exists in the method which has been used to calculate the actual costs of hospital services, particularly services that require costly implants. The approach used by CMS is to apply an overall ratio of costs to charges to individual devices. First, the data used by CMS to calculate the ratio of costs to charges uses data that is severely outdated and does not represent the current cost of technology. The data used by CMS does not reflect the current cost of the drug eluting stents which are significantly more expensive than the bare metal stents. In fact, the average cost of drug eluting stent is approximately three to four times the cost of the bare metal stent. An additional problem with the cost based methodology is that the typical patient is in the hospital for a shorter period of time than the typical patient. If the cost to charge ratio is applied to the total stay, the calculation of the payment rate applied to the total stay will be reduced since the ratio of costs to charges applied to ancillary services is typically less than the costs to charge ratio applied to routine services. It unclear whether the true costs of the cath lab or operating room equipment is completely reflected in the costs of the ancillary services for caths, angioplasties, open-heart surgery an orthopedic surgery. Another problem with this methodology is that the ratio of cost to charges varies widely on individual line items, with the levels of mark-up being significantly lower on high cost devices. Thus, the methodology does not recognize the fact that the cost of high charge devices as a percentage of charges is typically much less than the average cost to charge ratio for the overall organization. This results in reimbursement rates that are significantly understated and do not reflect our costs.

I greatly appreciate your consideration of our concerns, and would recommend that you refine the cost determination for procedures utilizing high cost devices, and consider exempting non-profit community hospitals from these reductions as they are not the intended target for corrective action as a result of documented abuses.

Sincerely,

David J. Robertson
President and CEO
Monongalia Health System

cc: Senator Robert Byrd
Senator John D. Rockefeller
Representative Alan B. Mollohan
Representative Nick J. Rahall II
Representative Shelly Moore Capito
Sonia D. Chambers, Chair WV Healthcare Authority
Sam G. Kapourales WV Healthcare Authority
Marilyn G. White WV Healthcare Authority

155

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Richard H. Anderson Chief Executive Officer
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June 9, 2006

BY HAND DELIVERY

Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1488-P (Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates)

Dear Administrator McClellan:

Ingenix, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule related to the fiscal year ("FY") 2007 inpatient hospital prospective payment system (" Proposed Rule").[1] As a company dedicated to transforming organizations and improving health care through information and technology, we have been involved with the inpatient hospital prospective payment system ("IPPS") since the advent of the diagnosis related groups ("DRGs"). In many ways, companies like ours represent the foundation of the Medicare prospective payment system since hospitals and Medicare Advantage plans alike rely on us to provide the software and services that they need to ensure proper coding and billing for Medicare inpatient stays. The purpose of this letter is to propose a strategy whereby CMS can implement both severity-adjusted DRGs and its proposal for a new DRG weight methodology, as early as October 1, 2006, without disrupting the normal course of business among Medicare providers and Medicare Advantage plans.

For numerous reasons explained below, we do not believe that it is feasible for CMS to refine the DRGs in FY 2007 based on the methodology in the Proposed Rule. However,

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[1] 71 Fed. Reg. 23996 (Apr. 25, 2006).

we believe that there is an alternative methodology that would work in the required timeframes, and we describe this methodology below and in the attached document entitled "The Ingenix Response to the CMS Request for Alternatives to Consolidated Severity-Adjusted DRGs" ("Ingenix Response"). To help CMS evaluate this methodology, Ingenix arranged with The Lewin Group ("Lewin") to undertake an independent evaluation of our strategy as well as a comparative analysis of this strategy based on the All-Payer Severity-Adjusted DRGs® ("APS-DRGs®") to the proposed consolidated severity-adjusted DRGs ("CSA-DRGs"). After a careful assessment, the Lewin report (attached), on page iv, concludes:

> [T] the modified APS-DRGs are worthy of consideration by CMS as an alternative to the proposed CSA-DRGs. They offer a simpler, more transparent, and perhaps more accurate approach by essentially extending CMS' approach to DRGs . APS-DRGs are statistically sound, offer system stability and flexibility over time, and are both precise and comprehensive.

Lewin reaches this decision in part because of the capacity of Medicare Modified APS-DRGs® to systematically predict treatment costs. On page 12 of the report deals with the relationship between casemix indexes and costs per case and states, in part:

> Because IPPS payment is proportionate to casemix but the regression implies a more-than-proportionate relationship between cost and casemix, high-casemix hospitals are being underpaid relative to low-casemix ones, even after accounting for the add-on payments for teaching and disproportionate share percentage. This problem would be substantially greater under CSA-DRGs than under modified APS-DRGs.

While CMS has requested suggestions for alternatives to its proposed CSA DRGs, it has yet to articulate the criteria it plans to use in evaluating such alternatives. ***Ingenix requests that CMS do so as soon as possible during the rulemaking process and, certainly, prior to issuing a Final Rule that substantially modifies the current DRG classification system.***

I. CMS' Proposed Methodology for Refining the DRGs Should Not be Implemented in FY 2007

Ingenix does not believe that it would be feasible for CMS to implement the new weight methodology and the proposed CSA-DRGs concurrently for FY2007. We believe that the complexity of the proposed CSA-DRG algorithm, as well as the limited amount of time generally available from issuance of the IPPS final rule until October 1 (about 60 days), is not sufficient for hospitals and Medicare Advantage plans to address the many challenges of implementing the CSA-DRGs. Our concerns on this issue are fully explained in a separate letter that addresses the issues of timing, as well as transparency.

In addition to the issue of transparency, there are some very practical reasons why a long lead time will be required to implement the CSA-DRGs. The most important is that the proposed CSA-DRGs are not an extension or enhancement of the current CMS DRGs. They are a complete replacement of the current CMS DRGs. Based on the All Patient Refined DRGS ("APR-DRGs"), the CSA-DRGs include, for example, a new set of base DRGs, new rules for assigning base DRGs, new surgical hierarchies, a de-emphasis of the traditional importance of principal diagnosis in driving DRG assignment, and a different list of operating room procedures. Once a case is assigned to an initial casemix category, the exceptions logic built into the CSA-DRGs can reassign the case to an different category associated with an entirely different body system. The algorithms that govern this exceptions logic as well as the rules for promoting and demoting secondary diagnoses to recognize severity are not intuitively obvious and differ depending on the patient's base DRG, age, principal diagnosis, operating and non-operating room procedures, age and more. In fact, the CSA-DRG methodology is so fundamentally different that it is not possible to crosswalk the current CMS DRGs to this proposed grouping methodology. The industry needs time to learn and evaluate this completely new DRG system.

The feasibility of adopting CSA-DRGs by October 2006, is further compounded by the fact that there is currently only one source for software and services relating to APR-DRGs, the foundation of the CSA-DRG system. Because no other software vendors or consultants have been enabled to support CSA-DRGs, it will be virtually impossible for these vendors and consultants to assist their clients in preparing for CSA-DRGs. More importantly, it will be virtually impossible for IT vendors to implement and deploy software products to support the CSA-DRGs in the sixty day period between publication of the final rule, when we expect the issue of transparency to be addressed, and the October 1, 2006 start of the fiscal year. In the short run, implementation of CSA-DRGs would provide a tremendous competitive advantage to hospitals that have historically used 3M software and APR-DRGs to assist their Health Information Management ("HIM") departments.

II. Strategy for Implementing DRG Refinement in FY 2007

While Ingenix does not believe it is feasible to refine the DRGs in the upcoming fiscal year using the APR-DRGs, we recognize that CMS faces considerable pressure to adopt a severity-adjusted DRG system at the same time that it implements its proposal for Hospital Specific Relative Value Cost Center ("HSRVcc") weights. Both the Medicare Payment Advisory Commission ("MedPAC") and some in Congress have called for concurrent implementation.

We believe that the only realistic strategy for simultaneously implementing HSRVcc weights and severity-adjusted DRGs is to move incrementally from the current DRG system. In effect, the single most important problem with CSA-DRGs, from a FY 2007 implementation standpoint, is that they represent an entirely new approach to casemix classification, which has been developed without public input. Rather than

replace the current DRG system, we recommend that CMS *enhance* the current DRG system to incorporate a severity-adjustment clinical model. This is the same approach that CMS considered when it proposed adoption of the Severity-adjusted DRGs in the mid 1990s. Given the incremental nature of this change, it can be accomplished without substantial disruption to the industry. Yet, it will achieve very significant improvements in the performance of the DRG grouper and it can pave the way for a more thorough and comprehensive review of the grouper methodology, in a timeframe that allows for thoughtful comments from all industry segments.

Ingenix currently offers a casemix classification system, the APS-DRGs®, that can serve as the basis for this type of incremental enhancement of the current CMS DRG system. APS-DRGs® are an all-payer generalization of the CMS Severity-adjusted DRG system, which, as is detailed in the enclosed evaluation, outperforms the proposed CSA-DRGs. APS-DRGs® utilize the current CMS DRG grouper as their base, and enhance upon this model by consistently applying a three-level severity subclass to individual DRGs or combinations of closely-related DRGs. This means, for example, that most CMS DRGs that do not involve a "CC/noCC" split are assigned to one of three terminal categories based on (1) the CMS DRG to which they are assigned and (2) the presence or absence of a CC or a Major CC.[2] We have updated the methodology every year since its inception, incorporating all changes which Medicare and the industry felt were appropriate. This means that the APS-DRGs® are compatible with the current version 23 of the CMS grouper, have a framework which is easily understood, and can be crosswalked to the current CMS DRGs. Because APS-DRGs® build off of the CMS DRG system, they do not require any significant training of coding professionals; the methodology can be deployed in essentially the same manner as the current CMS DRG grouper; and APS-DRGs® will provide a smooth, longitudinally compatible series of DRG groupers over time.

There are two, relatively minor issues that would need to be addressed to make this proposal work. One involves the CC and Major CC lists associated with APS-DRGs®. Because these lists were adapted from CMS Severity-adjusted DRG research, they incorporate slight differences from the current CC list used by the CMS DRGs. We believe that it would be prudent, as an initial step in enhancing CMS DRGs, to modify the CC and Major CC lists used by APS-DRGs® so that they are entirely consistent with the current CMS grouper. That is, every CC under the proposed v24.0 CMS grouper would be considered a CC or a Major CC under APS-DRGs®; any diagnosis that is not a CC under the proposed v24.0 CMS grouper would not be a CC or a Major CC under APS-DRGs®. The second issue involves the number of terminal categories in the current APS-DRG® system, which is currently 1,154. Although the preponderance of our technology partners can accommodate a four-digit DRG number, Ingenix will work with CMS to modify the current system of APS-DRGs® to reduce this number to less than 1,000. We believe this goal can be attained with relatively minor changes to the system,

[2] In this document, "CC" refers to complications or comorbidities; a major complication or comorbidity is referred to as "MCC", and "NCC".

specifically by aggregating DRGs that rarely occur in the Medicare population and only applying the severity model to DRGs where it is clinically appropriate.

Implementation of the base APS-DRGs® system in FY 2007 (October 1, 2006) could serve as the first step in a long-term strategy to overhaul the CMS DRG system along the lines recommended by MedPAC. The attached document, entitled "The Ingenix Response to the CMS Request for Alternatives to Consolidated Severity-Adjusted DRGs", describes our alternative to Consolidated Severity-Adjusted DRGs that will be more effective in accomplishing the long-term objectives of CMS with less disruption to the hospitals and Medicare Advantage plans upon which CMS depends. Our proposal details the phased approach described above with additional enhancements that addresses the issue of multiple coexisting clinical conditions, the issue that underlies calls for a severity-adjusted DRG system, in a simple and straightforward manner.

We envision a two-stage transition process that would eventually lead to implementation of a substantially improved set of CMS DRGs that incorporate a severity-adjustment algorithm that is demonstrably superior to the proposed CSA-DRGs. The first step is outlined above and would involve simple modifications to the current CMS DRG system based on our APS-DRGs® methodology. Because the first step represents a relatively small modification to the current DRG system and would be fully consistent with that system in terms of basic grouping logic, it could easily be implemented on October 1, 2006. The second stage of this transition would then be addressed during FY 2007 with an anticipated implementation date of October 1, 2007. During this period, Ingenix would work with CMS to undertake a comprehensive review of the CC and Major CC code lists, as well as the exclusion logic that is designed to ensure that only independent clinical conditions are recognized for casemix classification purposes. We would also work with CMS to implement our proposal for case-specific weights, which we believe is fundamentally the most appropriate strategy to control for severity among hospitalized patients.

Ingenix shares the CMS commitment to ongoing improvements in the casemix classification used by the Medicare program for determining inpatient hospital reimbursement. However, we firmly believe that the proposal to implement CSA-DRGs is the wrong strategy for CMS to pursue for the reasons outlined above and described in more detail in the attached document. The alternative that we are presenting offers CMS the opportunity to implement severity-adjusted DRGs in FY2007 with a minimum of disruption to the healthcare industry and the Medicare program. It also creates the opportunity to implement in FY2008 additional enhancements to the current CMS DRG system that will result in a severity-adjusted DRG methodology that will outperform CSA-DRGs in all important clinical and financial respects. Moreoever, we believe that our proposal will simplify the challenge of modifying the inpatient casemix classification system to accommodate the transition from ICD-9-CM to ICD-10.

Indeed, we asked the Lewin Group to conduct a comparison of the APS-DRGs® (modified as described above) and the CSA-DRGs to test our belief that the former will outperform the latter. The attached report confirms our belief. While the report speaks

for itself on this question, we note a number of the more pertinent findings concerning the modified APS-DRGs®:

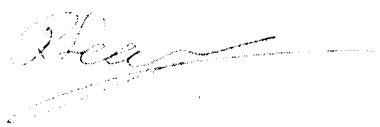
- They explain at least as much variance in patient severity as the CSA-DRGs and are simpler and more flexible;
- They are more transparent;
- They are easier for hospitals to implement; and
- They are easier to maintain and improve over time.

In our view, this independent evaluation from the Lewin Group provides important validation of our suggested strategy for implementing DRG refinements.

Ingenix is prepared to provide CMS with an open-source license to the modified APS-DRG methodology for its use. We would make the methogology available to hospitals and Medicare Advantage plans in a fully transparent fashion for nominal royalty fees similar to what one would pay for the current CMS DRGs from NTIS exclusive of software fees levied in the normal course of business. In addition, Ingenix will collaborate with IT vendors to ensure that all vendors have access to the methodology and the opportunity to compete in the open market. Lastly we will open the methodology up to public discussion and comment guided by CMS reconciliation and decisionmaking.

I would welcome the opportunity to meet with you and to discuss these ideas further. Ingenix understands that there is relatively little time for CMS to implement any type of severity-adjusted DRGs for October 1, 2006. Consequently, we are prepared to work with CMS at our own expense to implement the changes to the APS-DRGs® identified above and to assist with the timely implementation of our proposal.

Sincerely,



Robert Leary
Vice President, Ingenix

Attachments

INGENIX®

The INGENIX® Response to the CMS Request for Alternatives to Consolidated Severity-Adjusted DRGs

June 12, 2006

400 Capital Boulevard, Rocky Hill, CT 06067
20010 Century Boulevard, Suite 103, Germantown, MD 20874

APPENDICES

1 Introduction

In its Notice of Proposed Rulemaking (NPRM) for the Fiscal Year 2007 Inpatient Prospective Payment System, published on April 25, 2006, the Centers for Medicare and Medicaid Services (CMS) explicitly requested suggestions for alternatives to its proposed system of Consolidated Severity-adjusted DRGs (CSA DRGs). Subsequently, this same request was repeated in the Open Door Forum that CMS held on May 5, 2006. HSS, an operating unit of Ingenix (referred hereinafter as Ingenix) that is devoted to developing and deploying software and services to assist the healthcare industry with coding, compliance and reimbursement management submits this document in support of its comments in response to these requests from CMS.

Ingenix fully supports CMS in its efforts to refine the DRG classification system by introducing severity-adjustment into the current system. However, we believe that moving forward with the proposed CSA DRGs would be a mistake for a number of reasons including its lack of transparency and the fact that it represents a wholesale replacement of the current methodology. As an alternative, Ingenix recommends that CMS consider a two-part strategy based on our All-Payer Severity-adjusted DRGs® system (APS-DRGs). Unlike CSA DRGs, our proposal is fully transparent and enhances, rather than replaces, the current CMS DRGs. It offers numerous other advantages to CMS in that it:

- Outperforms CSA DRGs both clinically and statistically;
- Is easier to implement and, for that reason, will meet with greater acceptance across the industry;
- Is easier to operate and will have less impact on coding and billing productivity;
- Simplifies the transition to ICD-10; and,
- Provides CMS with a clear strategy to implement severity-adjusted DRGs in FY2007, if it chooses to do so.

FY 2007 implementation can occur without significant disruptions among hospital providers or Medicare Advantage plans and without compromising the long-term goal of implementing the most appropriate and effective severity-adjustment system in the Medicare program.

The proposal that we describe below will help CMS avoid many problems with the current CMS proposal for CSA DRGs. The CMS proposal is entirely dependent on a casemix classification system, All-Patient Refined DRGs (APR-DRGs), that is a proprietary product of 3M Health Information Systems (3M). Neither CMS nor 3M has given any indication that this methodology will be available to the industry in a transparent manner that would enable any organization other than 3M to provide software or services relating to the proposed methodology. Indeed, experience from the State of Maryland suggests that the use of APR-DRGs by the Medicare program will lead to significant increases in software license fees and anti-competitive market behavior by 3M. The Ingenix proposal explicitly includes the type of transparency that has traditionally been associated with the CMS DRG system.

In addition, the Ingenix proposal is designed to *enhance*, rather than *replace*, the current system of CMS DRGs. APR-DRGs differ radically from the current DRGs used by CMS to reimburse hospitals. APR-DRGs are not built upon the CMS DRGs and, as a result, the base classifications of the APR-DRGs are vastly different from those used by CMS. In addition, the APR-DRGs use different rules to determine complications and comorbidities (CCs), operating room procedures, and even Major Diagnostic Categories (MDCs). They also employ complicated exceptions and re-routing logic that has no precedent within the current DRG system and frequently reclassify discharges across severity levels, DRG categories and MDCs. For these reasons, coders and other health information management professionals require considerable training and education before they can assign ICD-9-CM diagnosis and procedure codes to cases in a way that ensures proper payment under a CSA DRG-based payment system. In fact, the State of Maryland required 3M to conduct a series of educational sessions in advance of implementing APR-DRGs for rate-setting purposes precisely because of these differences. By enhancing the current CMS DRGs, our proposal will substantially simplify the transition process for the industry.

Finally, we believe that our proposal will provide CMS with a simpler transition to ICD-10 than CSA DRGs. APS-DRGs rely on a uniform algorithm for establishing severity levels and minimize exceptions logic. As such, any change from ICD-9-CM to ICD-10 can be accomplished through relatively straightforward mapping of ICD-10 to ICD-9-CM codes. While we expect that the transition for CSA DRGs would also be accomplished initially through code-mapping, the complex algorithms, re-routing and exceptions logic used by CSA DRGs to determine severity levels will require extensive analysis to ensure that the applied code mapping achieves expected and consistent results throughout the algorithm. One can anticipate that a far more detailed and complicated crosswalk will be required to support CSA DRGs and that such a crosswalk will be more sensitive to the inherent error embodied in such a mapping process.

2 Ingenix Proposal

The alternative strategy for severity-adjusting DRGs that is described below is derived from Ingenix's All-Payer Severity-adjusted DRGs, a casemix classification system that has been available in the market for more than 10 years. Our proposal for "Medicare Modified APS-DRGs" (MM APS-DRGs) offers many advantages to CMS over its current proposal for Consolidated Severity-adjusted DRGs (CSA DRGs). In fact, we believe it is superior to CSA DRGs on virtually all dimensions along which alternative methodologies should be evaluated.

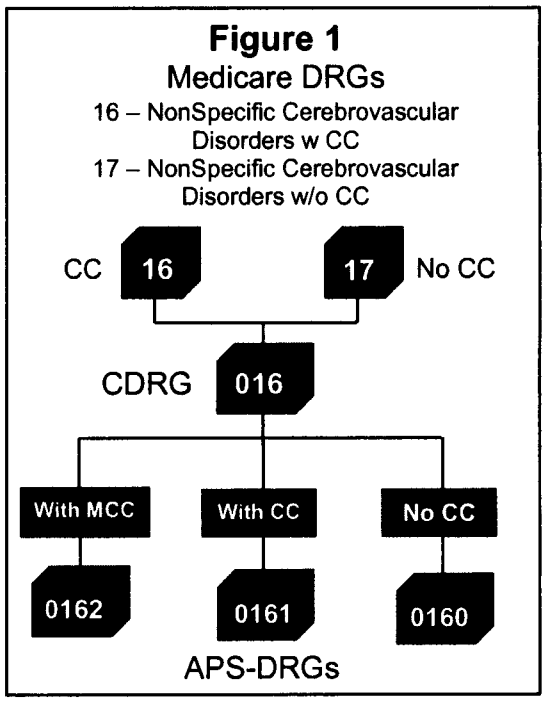
2.1 Medicare Modified APS-DRGs

APS-DRGs were developed by HSS, Inc., (HSS) in 1994 as a methodology for identifying and categorizing patients with different levels of resource needs and different outcomes. At the time, HSS envisioned that APS-DRGs would be used primarily for outcomes and performance evaluation purposes. The APS-DRGs are based upon research that CMS conducted for the purpose of developing a severity-adjusted set of DRGs appropriate for use in the Medicare inpatient prospective payment system. HSS generalized and enhanced the CMS methodology so that it could be applied to non-Medicare, all-payer patient populations. It has updated the methodology annually, to ensure that APS-DRGs remained consistent with the underlying CMS DRG

methodology. When Ingenix acquired HSS in 2005, Ingenix assumed responsibility for maintaining APS-DRGs. APS-DRGs today represent a logical extension of the current version 23 CMS DRGs.

Figure 1 illustrates the basic strategy that APS-DRGs use to enhance CMS DRGs. First, the methodology defines a set of Consolidated DRGs (CDRGs) by combining closely related DRGs or DRGs that are distinguished solely by a CC/No CC split. In this example, DRGs 16 and 17 (Nonspecific Cerebrovascular Disorders with and without CC) are combined into CDRG 16. Once a case is assigned to a CDRG, the methodology reviews every secondary diagnosis to determine if it is a CC or a Major CC, applying standard Medicare exclusion logic. The case is then assigned to a terminal category based on the most important secondary diagnosis using a consistent three-level severity model (Major CC, CC, No CC). Finally, after a case is assigned to a terminal category, a weight is attached that indicates the expected relative resource requirements associated with the discharge.

Figure 1



The process used by HSS to develop and maintain APS-DRGs is based on several fundamental principles. Specifically, APS-DRGs are designed to:

- Remain materially compliant with the underlying DRG structure used by CMS in the Medicare program, which is familiar to hospital coders and billers;
- Rely only on administrative data routinely collected by hospital abstracting and billing systems;
- Be intuitively reasonable, clinically coherent, and statistically powerful;
- Represent severity with a uniform clinical structure;
- Incorporate an innovative and extremely powerful neonatal model;
- Define severity classes based on clinical conditions and ***not*** treatment decisions;
- Measure casemix with a parsimonious number of categories;
- Incorporate annual revisions reflecting changes in ICD-9-CM codes, Medicare DRGs, clinical practice, and technology; and
- Be compatible with such diverse applications as clinical performance measurement, provider profiling, financial analysis, and per-case reimbursement.

The Medicare Modified APS-DRGs that we are proposing to CMS incorporates the following three simple modifications to the core system of APS-DRGs:

- Systematic reductions in the number of terminal categories used by APS-DRGs based upon patterns of hospitalization observed in the Medicare population to address CMS' objective of fewer than 1000 terminal groups;
- Case-specific weights that use all relevant clinical information to measure severity thereby addressing the potential for providers to "cherry-pick" among cases based on the absence of coexisting clinical conditions; and
- A crosswalk between our current nomenclature, which uses a four-character designation to distinguish between the underlying CMS DRG and the appropriate severity level, to a new three-character designation that would be compatible with current data base structures.

2.2 Comparative Performance

Ingenix examined the implications of our proposal compared to the current CMS DRGs and the proposed CSA DRGs, using the 2004 MedPAR file released by CMS in conjunction with FY2007 proposed rule. This case-level analysis, which is described more fully in Section 6, focused on "Standardized Total Charge" (STC), which we define as the total charge for a claim, adjusted for differences across hospitals in labor costs, indirect medical education, and disproportionate share.[1]

We analyzed three specific casemix classification systems: CMS DRGs (v22.0), CSA DRGs, and Medicare Modified APS-DRGs (v23.0). For each, we developed weights based on STC per case and then analyzed the extent to which those weights successfully "explained" variations in STC across discharges in the MedPAR file. Our weights for CMS DRGs and CSA DRGs were estimated at the level of the terminal categories of each system. This means that every case assigned to a particular CMS DRG or a CSA DRG was assigned the same weight. This is the traditional weight estimation approach used in conjunction with DRGs and the only procedure compatible with the information available from MedPAR for these two systems. Our MM APS-DRG weights are case-specific, in the sense that they vary across cases within a terminal category based on the additional clinical characteristics of each case.

The results of the analysis described above are summarized in Table 1, which examines the variation in standardized total charges per case that are statistically explained by each of the three methodologies. Results are shown overall and by individual Major Diagnostic Category.[2]

[1] The analysis focuses on STC rather than cost because of the limited time available for cost-finding and subsequent analysis. We are confident that a more extensive comparative analysis that included detailed, department-level cost finding would yield results that are qualitatively similar to those reported here. The work summarized by Lewin and Associates in their accompanying report supports this expectation.

[2] For this analysis, DRGs assigned during pre-MDC processing are treated collectively as a separate MDC. The analysis excludes the handful of cases assigned to MDC 15 (Neonates) as well as discharges from hospitals that are not subject to inpatient PPS.

Table 1. Percent of Variance in Standardized Total Charges Explained by Casemix Classification Systems, Total and by MDC

MDC	Description	No. of Discharges*	CMS DRGs	CSA DRGs	Medicare Modified APS-DRGs
Total		11,935,214	**33.54%**	**40.79%**	**43.47%**
00	Cases Grouped Prior to MDC Processing	136,972	32.16%	33.85%	38.76%
01	Diseases and Disorders of the Nervous System	915,389	17.46%	28.90%	31.49%
02	Diseases and Disorders of the Eye	14,609	3.45%	17.30%	17.21%
03	Diseases and Disorders of the Ear, Nose, Mouth and Throat	106,446	7.52%	19.65%	21.87%
04	Diseases and Disorders of the Respiratory System	1,772,026	17.62%	28.01%	27.34%
05	Diseases and Disorders of the Circulatory System	3,359,611	38.86%	47.03%	48.31%
06	Diseases and Disorders of the Digestive System	1,292,093	21.16%	35.04%	38.74%
07	Diseases and Disorders of the Hepatobiliary System and Pancreas	340,791	11.78%	26.03%	31.08%
08	Diseases and Disorders of the Musculoskeletal System and Connective Tissue	1,333,530	21.32%	30.23%	33.56%
09	Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast	291,224	9.00%	19.10%	23.15%
10	Endocrine, Nutritional and Metabolic Diseases and Disorders	474,253	9.57%	21.58%	25.07%
11	Diseases and Disorders of the Kidney and Urinary System	666,883	17.41%	28.45%	31.58%
12	Diseases and Disorders of the Male Reproductive System	103,548	8.41%	21.44%	24.62%
13	Diseases and Disorders of the Female Reproductive System	125,771	10.27%	25.50%	29.20%
14	Pregnancy, Childbirth and the Puerperium	14,498	8.38%	23.55%	24.43%
16	D&D of Blood and Blood-Forming Organs, Immunological Disorders	156,587	3.99%	13.03%	13.39%
17	Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms	101,955	8.86%	22.75%	26.66%
18	Infectious and Parasitic Diseases (Systemic or Unspecified Sites)	350,442	9.26%	20.79%	25.53%
19	Mental Diseases and Disorders	113,471	3.50%	7.54%	8.80%
20	Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders	57,943	4.94%	18.25%	21.89%
21	Injuries, Poisonings and Toxic Effects of Drugs	126,604	10.38%	27.00%	32.63%
22	Burns	4,817	23.74%	30.65%	26.28%
23	Factors Influencing Health Status and Other Contacts with Health Services	45,733	5.10%	15.08%	17.69%
24	Multiple Significant Trauma	11,164	11.04%	24.05%	24.21%
25	HIV Infection	18,853	6.84%	17.53%	21.70%

* Excludes discharges that are not paid under the Medicare hospital inpatient prospective payment system.

As Table 1 demonstrates, the proposed Medicare Modified APS-DRGs substantially outperform either of the other methodologies both overall and by MDC. MM APS-DRGs have an overall R-Squared of 43.47 percent, compared to 40.79 percent for the CSA DRGs and 33.54 percent for Medicare DRGs. Within individual MDCs, the R-Squared statistic ranges from lows of 8.8 percent in MDC 19 ("Mental Diseases and Disorders") and 13.39 percent in MDC 16 ("Diseases and Disorders of Blood and Blood Forming Organs and Immunological Disorders") to highs of 38.74 percent in MDC 06 ("Diseases and Disorders of the Digestive System") and 48.31 percent in MDC 05 ("Diseases and Disorders of the Circulatory System"). Medicare Modified APS-DRGs even explain 38.76 percent of the variation in standardized total charges among cases that are assigned to DRGs during pre-MDC processing. Even more noteworthy is the fact that MM APS-DRGs outperform CSA DRGs in every MDC except one, MDC 22 ("Burns"), which contains the fewest discharges and as a result the most volatile statistical estimates.[3]

Table 2.
Effect of Classification System on Casemix Index, by Teaching Status and Location

		Estimated Casemix Indexes			Pct. Change from CMS v23	
	No. of Hospitals	CMS v22 DRGs	CSA DRGs	MM APS-DRGs	CSA DRGs	MM APS-DRGs
Non-Teaching Hospitals	2,458	0.9303	0.9214	0.9195	-0.96%	-1.16%
Resident/Bed < .10	563	1.0483	1.0545	1.0527	0.59%	0.42%
Resident/Bed > .10	516	1.1304	1.1418	1.1469	1.01%	1.46%
Rural	1,025	0.8384	0.8121	0.8041	-3.13%	-4.09%
Small Urban	1,150	1.0546	1.0507	1.0447	-0.36%	-0.93%
Large Urban	1,362	1.0302	1.0422	1.0500	1.16%	1.92%

Table 2 examines the alternative casemix classification systems in relation to teaching status and location. It shows that both CSA DRGs and MM APS-DRGs lower the casemix index of non-teaching hospitals while increasing the CMI for teaching facilities and, especially, large teaching hospitals. While both refined methodologies amplify current CMI patterns, MM APS-DRGs generally have a slightly larger effect. Similarly, both CSA DRGs and MM APS-DRGs tend to lower the CMI at rural hospitals and at small urban facilities. Both raise the CMI on average in large urban hospitals. However, it is interesting to note that, while the differences are small, the direction of the effect on casemix in large urban areas depends upon the method. Both CMS DRGs and CSA DRGs show a slight decline in the CMI, moving from small urban areas to large ones; MM APS-DRGs show a slight increase.

[3] The outstanding empirical results associated with MM APS-DRGs® are not solely the result of case-specific weights. Even with traditional, cell-specific weights, APS-DRGs® achieve an R-Squared of 38.60 percent. Simply distinguishing among baseline cases and discharges with one or more "unused" CCs, one or more unused Major CCs, or both, out-performs the proposed system of consolidated severity-adjusted DRGs.

Table 3.
Effect of Classification System on Casemix Index, by Size and Urban-Rural Status

	No. of Hospitals	CMS v22	CSA DRGs	MM APS-DRGs	Pct. Change from CMS v23 CSA DRGs	Pct. Change from CMS v23 MM APS-DRGs
Urban						
0-99	571	0.9092	0.9455	0.9448	3.63%	3.56%
100-199	865	0.9214	1.0141	1.0123	9.27%	9.08%
200-299	488	1.0070	1.0768	1.0857	6.99%	7.87%
300-499	420	1.1004	1.1502	1.1526	4.98%	5.21%
500+	168	1.1787	1.1864	1.1928	0.77%	1.41%
Rural						
0-49	365	0.7192	0.6740	0.6637	-4.52%	-5.55%
50-99	372	0.7867	0.7553	0.7465	-3.13%	-4.02%
100-149	178	0.8436	0.8199	0.8127	-2.37%	-3.09%
150-199	64	0.9100	0.8939	0.8865	-1.61%	-2.36%
200+	46	0.9924	0.9818	0.9754	-1.06%	-1.70%

Table 3 presents similar statistics for hospitals by bed size and location. Again, the results show that CSA DRGs and MM APS-DRGs have similar effects, relative to the CMS DRG system. Smaller rural hospitals generally have larger reductions in casemix, although reductions in casemix at rural hospitals occur across all bed size categories. The picture is less uniform among urban hospitals, where the smallest increases in casemix occur at the largest hospitals (500 or more beds) and the largest increases are associated with the 100-199 bed tier.

These results demonstrate that MM APS-DRGs will achieve the same set of basic policy goals that motivated the original Medicare proposal for CSA DRGs. At the same time, MM APS-DRGs appear to be more successful in discriminating among patients based on expected resource use. For these reasons, the aggregate effect of MM APS-DRGs is very comparable to that of CSA DRGs although MM APS-DRGs appear to be slightly more effective at redirecting revenues to hospitals with higher expected resource requirements.

2.3 Benefits of MM APS-DRGs

On balance, MM APS-DRGs provide CMS with an alternative casemix classification system that is superior to CSA DRGs because MM APS-DRGs will be:

- Less disruptive to current operations in hospitals, Medicare Advantage plans, and even CMS itself;
- More powerful in discriminating among cases based on the resources that are required for clinically appropriate treatment;
- Comparable to CSA DRGs in reallocating dollars across the hospital industry; and
- Easier to maintain over time, especially during the transition to ICD-10.

Another advantage of the Ingenix proposal is that it offers CMS an opportunity to implement severity-adjustment for FY2007, if it chooses to do so. In particular, adopting MM APS-DRGs would enable CMS to undertake a two-step transition. Phase 1, which could be completed in time for the publication of a Final Rule in August, would implement a modified version of the current APS-DRG methodology with cell-specific weights. In this phase, Ingenix would work with CMS to:

- Modify APS-DRGs so that they use the same (or at least a comparable) CC list as the current CMS DRGs,
- Stratify the CMS CCs into the CC and MCC tiers of the APS-DRG methodology and apply the severity model consistently across the DRG system,
- Implement the terminal group consolidation described in Section 5 below to ensure that the final number of terminal categories is less than 1,000, and
- Create a crosswalk from the current 4-character APS-DRG nomenclature to a three-digit numbering scheme.

These modest steps will result in a substantial improvement in the ability of the CMS DRG system to allocate dollars based on expected resource requirements. Our analysis of the 2004 MedPAR file shows that APS-DRGs, even without case-specific weights, explain 38.60 percent of the overall variation in standardized total charges across cases. This approaches the effectiveness of the fully implemented CSA DRG system. Case-specific weights increase this figure to 43.47 percent.

The second phase of our proposal will strengthen MM APS-DRGs by incorporating various modifications based on MedPAC recommendations for severity-adjusted DRGs. Specifically, Ingenix will work with CMS to re-evaluate CC and Major CC lists and to enhance the current CC exclusion logic to ensure that only independent coexisting clinical conditions are recognized by the methodology. Once this task is complete, we will incorporate case-specific weights into the MM APS-DRGs. As described more fully below, case-specific weights adjust the weight assigned to a discharge as a result of its casemix classification based on the presence of additional independent coexisting clinical conditions. Because it controls explicitly for clinical factors that are not recognized by the current CMS DRGs, MM APS-DRGs with case-specific weights substantially reduce the potential for providers to cherry pick among patients based on unmeasured differences in severity. This method will also address the desire of coders in the HIM profession to ensure that more clinical information is recognized by the casemix classification process.

3 Criteria For Evaluating Proposals To Severity-Adjust Medicare DRGS

As noted earlier, CMS explicitly requested suggestions for alternatives to Consolidated Severity-adjusted DRGs at least twice in recent months. One request was contained in the April 25, 2006, NPRM. 71 Fed. Reg. at 24011. This request was repeated publicly, during the Open Door Forum that CMS held on May 5, 2006. Despite these requests, CMS has yet to articulate the criteria it plans to use in evaluating such alternatives. ***Ingenix requests that CMS do so as soon as possible during the rulemaking***

process and, certainly, prior to issuing a Final Rule that substantially modifies the current DRG classification system.

To assist in that effort, Ingenix reviewed previous statements about evaluation criteria. The clearest statement regarding such criteria was made by CMS (then HCFA) in discussions about its proposal for Severity-adjusted DRGs (SDRGs) that was released in 1994.[4] Since the primary purpose of DRGs is to determine hospital reimbursement, it stands to reason that the most important attribute of a DRG system is its ability to discriminate among discharges in terms of resource use and to direct reimbursement across cases (and hospitals) based on relative resource requirements. A second characteristic to consider is the stability of the system, i.e., the predictability of reimbursement over time for services where underlying technologies do not change significantly. Clearly, any empirical process for estimating DRG weights will be subject to random fluctuations in data from one data set to another. However, it is reasonable to expect that a DRG system should support statistically reliable estimation procedures that minimize the substantive importance of such fluctuations.

Another important consideration – and a direct consequence of concern over the stability of the system, is the number of terminal categories created by the DRG system. Under standard DRG-based payment methods, separate "weights" are estimated for each terminal category in the system; reimbursement for any individual case is then determined by multiplying the weight of the category to which it is assigned by a "conversion factor" that reflects the costs of care for an average or baseline case. Weights are usually based on statistical estimation of the typical costs of care for cases assigned to a specific terminal category relative to a baseline case. For this reason, every DRG system faces a tradeoff: increasing the number of terminal cases makes it possible to recognize more clinical factors likely to affect the costs of care but it also reduces the precision with which any particular weight is estimated.[5]

There is a second consideration associated with the number of terminal categories. Historically, every DRG system used for reimbursement has had fewer than 1,000 terminal categories. As a result, some DRG-related software, interfaces and database designs presume that a DRG can be represented by at most three numeric characters. While most of Ingenix's IT partners can accommodate a 4-digit DRG, expansion to more than 1,000 categories would require a significant financial investment for some IT vendors to redesign basic infrastructure and application software.

CMS also identified three other considerations in its 1994 report. One involved the costs, to CMS and to the industry as a whole, of adopting any new DRG system. Ideally, any proposed change to the current system of DRGs should minimize the extent to which Health Information Management (HIM) professionals need to be retrained, information systems need to be modified, or additional resources are needed to support the system. The second consideration involved the extent to which the system is vulnerable to manipulation. This means, for example, that providers should not be able to gain financially by withholding information about a patient or the services provided to a patient. At the same time, a well-designed casemix classification system should provide

[4] Health Care Financing Administration. "Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity." June 1994.
[5] Most DRG systems currently used for reimbursement involve between 500 and 600 terminal categories.

incentives for providers to disclose all relevant information about a case, because the clinical information on bills is the primary source of data available to payers. Complete and accurate clinical information is the only way that payers can evaluate provider performance, understand the clinical requirements of their covered populations, and manage their organizations in a way that is both financially and clinically appropriate.

Finally, CMS suggested that the design of any acceptable DRG system must be simple and valid on its face:

> In addition, we sought a system that would be seen as fair, nonpunitive, and easy to understand by hospitals, physicians, and beneficiaries. (CMS, page 13).

Based on these considerations, Ingenix suggests that the criteria for evaluating alternatives for severity-adjusting CMS DRGs can be grouped into three basic categories. In particular, any viable alternative must:

- Offer a strong value proposition to CMS and Medicare beneficiaries
- Possess a rigorous scientific foundation
- Have the capacity to achieve broad acceptance by hospitals, other health care providers, and Medicare Advantage plans that are the backbone of the Medicare system.

Each of these is discussed more fully below.

3.1 Strong value proposition for CMS.

Any alternative to the current CMS DRGs must substantially improve upon the ability of the CMS DRGs to explain variations across individual cases in the resources required for treatment. At the same time, CMS should be cautious that the structure of any new DRG system does not encourage unnecessary or wasteful treatment decisions and that the use of procedure codes to categorize patients is minimized. That is, the system should be statistically powerful in discriminating among patients based on their underlying clinical conditions while remaining neutral with respect to clinical decisions about the course of treatment.

At the same time, any alternative to the current CMS DRGs must offer a simple, straightforward transition strategy to CMS. To the extent possible, it should extend and enhance, rather than simply replace, current CMS methods. It should also be compatible with other CMS initiatives that require a casemix classification system including prospective payment for long-term acute care hospitals and for inpatient psychiatric facilities, as well as offer clinically defensible strategies to base reimbursement on outcomes and other measures of performance.

Finally, any alternative to the current CMS DRGs must be easy and efficient to maintain. It must be readily adapted to the requirements of new policy initiatives and it should accommodate emerging medical technologies to the extent that CMS chooses to recognize them for payment purposes. The system itself should be accessible to various CMS stakeholders and enable them to participate in an active and informed manner in any discussions about the need to adapt, enhance and otherwise modify the system in response to future requirements.

3.2 Rigorous scientific foundation.

Any viable alternative to the current CMS DRGs must be built on a strong scientific foundation that spans both clinical and behavioral research. In order to be clinically coherent, the methodology needs to incorporate distinctions between patients that are clinically meaningful and consistent with the current organization of medical practice in the United States. This means, for example, that it is appropriate to distinguish among cases based on body system involvement and whether or not the primary treatment is surgical in nature. At the same time, the system ought to provide incentives for providers to treat patients in a manner that is both clinically appropriate and efficient in terms of resource use. The system should not routinely *reward* the use of new technologies, regardless of efficacy or efficiency, but it should *enable* new technologies when clinically and financially appropriate.

The methodology also needs to support statistically robust estimation procedures. This means that CMS must be able to estimate weights, conversion factors and other payment parameters efficiently and precisely. It is also important for statistical estimates to be relatively stable over time. In general, the methodology needs to deliver weights and conversion factors that on average provide adequate but not excessive reimbursement to individual providers. At the same time, reimbursement for any individual case should be "fair" in the sense that it reflects the expected level of resources required for a hospital to care for the patient, given his or her underlying clinical condition.

Finally, the system should provide strong incentives for providers to code cases completely and accurately. Accurate and complete reporting serves important short and long-run objectives. In the short-run, it is essential for ensuring equity and accuracy in reimbursement calculations. In the long-run, it is the only way for Medicare to develop the information resources that it needs to allocate reimbursement dollars where they are most needed and where they will be used most effectively.

3.3 Capacity to achieve broad industry acceptance.

The third major dimension along which any alternative to the current CMS DRGs needs to be evaluated involves the extent to which the methodology has the capacity to achieve broad industry acceptance, especially by hospitals, clinical professionals, and Medicare Advantage plans. Experience has shown that simplicity and transparency are fundamental to such acceptance. That is, providers need to understand how a methodology works and what factors are responsible for the assignment of a case to a particular casemix category.

Beyond simply understanding the methodology, it is also important for providers and health plans to be able to replicate the methodology with a minimum of effort. This means that they need to be able to either develop their own version of a "DRG grouper" based on comprehensive information from CMS or to license software at reasonable fees on the open market.

Finally, industry acceptance will depend upon the costs that various stakeholders incur as a result of CMS decisions. Hospitals will certainly look at the implications of any CMS proposal along a number of dimensions. These include IT requirements, coder training

and education for proper coding and billing, impact on coder productivity, new physician documentation requirements, and other administrative costs associated with the proposal. Any proposal that creates excessive, new administrative burdens will run into serious opposition from hospitals and from the IT industry that serves them. The same is true for Medicare Advantage plans that represent a significant growing portion of the Medicare program.

4 Severity-Adjusting Medicare DRGs

4.1 Severity-adjustment Using SDRGs

The CMS DRGs designate approximately 3,000 diagnosis codes as substantial comorbid conditions or complications (CCs). These diagnoses cover a broad spectrum of disease conditions, ranging from major acute illnesses (e.g., heart attack and stroke) to minor illnesses (e.g., otitis media and urinary tract infections). The diagnoses designated as CCs are expected to increase the length of stay for 75% of the patients by at least one day. No other differentiation relative to severity or complexity is made among these diagnoses. The Severity-adjusted DRGs (SDRGs) that CMS developed in 1994 improved upon the original DRG definitions by dividing all secondary diagnoses into three categories: not a CC, a CC, or a Major CC. The Major CC category included significant acute diseases, as well as chronic diseases for which an acute exacerbation presented a significant problem for the patient. When compared to CCs, treatment of patients with Major CCs required a substantial amount of additional resources.

Under CMS's SDRG structure, all paired DRG groupings (DRGs with and without CCs) were consolidated. In addition, based on clinical judgment and statistical analysis, groups of DRGs were consolidated because they contained patients with similar clinical patterns and resource use. Each "Consolidated DRG" or CDRG was evaluated to determine if it should be split based upon the presence of a Major CC, a CC, both, or neither. "CC" splits (including splits into levels of CCs) were only made when they were associated with differences in resource use that met specific quantitative criteria. The resulting CMS model recognized four different severity-adjustment scenarios, as follows:

- The CDRG was split into three severity levels: (1) no CC, (2) with a CC, (3) with a Major CC;
- The CDRG was split into two severity levels: (1) no CC or a CC only (2) with a Major CC;
- The CDRG was split into two severity levels: (1) no CC (2) with a CC or a Major CC; or
- The CDRG was not split into any severity levels.

CMS used these four different severity approaches to reduce the number of terminal categories and to ensure that severity-adjusted categories corresponded to meaningful differences in outcomes. Unfortunately, the process used by CMS to collapse across severity-levels ignored statistically significant differences in outcomes. It also created a model that lacked a uniform clinical structure and was difficult for users to understand and remember. Finally, this approach tended to ignore small groups of clinically distinct patients because such groups were less likely to meet the specified quantitative criteria used to drive the collapse process. As a result, clinically distinct patients were often combined into a larger, heterogeneous group of patients.

4.2 Severity Adjustment Using APS-DRGs

APS-DRGs follow the current CMS DRG system by using diagnoses (both principal and secondary), as well as the occurrence and degree of surgery, as discriminating variables in assigning patients to broad discharge categories. In some instances, both methods also take into account the patient's age or discharge status. APS-DRGs then enhance the current CMS model by following the SDRG approach of dividing secondary diagnoses into severity levels. However, the APS-DRGs improve upon the SDRG model. The APS-DRGs use the same underlying structure of "Consolidated DRGs" (CDRGs) as the CMS model. CDRGs are then split into three resource-based severity levels: no CCs, with a CC, or with a Major CC. Unlike SDRGs, APS-DRGs do not then aggregate severity classes within a CDRG. As a result, the APS-DRGs begin with a nationally-recognized and clinically acceptable model and apply a uniform structure that is intuitively reasonable and easily explained. Figure 3-1 illustrates the basic methodology for severity-adjusting cases in the APS-DRG system for Medicare DRG 88, "Chronic Obstructive Pulmonary Disease (COPD)." By construction, DRG 88 becomes CDRG 088, which is in turn split into three distinct severity classes: COPD with a Major CC (APS-DRG 0882), COPD with a CC (APS-DRG 0881) and COPD without a CC or an MCC (APS-DRG 0880).

Figure 3-1
Medicare DRG
88 – Chronic Obstructive Pulmonary Disease

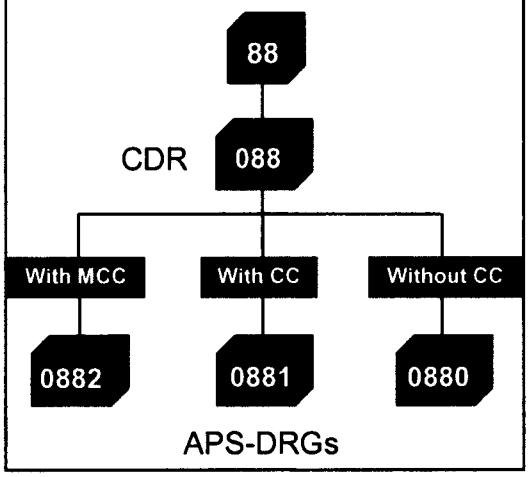


Figure 3-2
Medicare DRGs
16 – NonSpecific Cerbrovascular Disorders w CC
17 – NonSpecific Cerbrovascular Disorders w/o CC

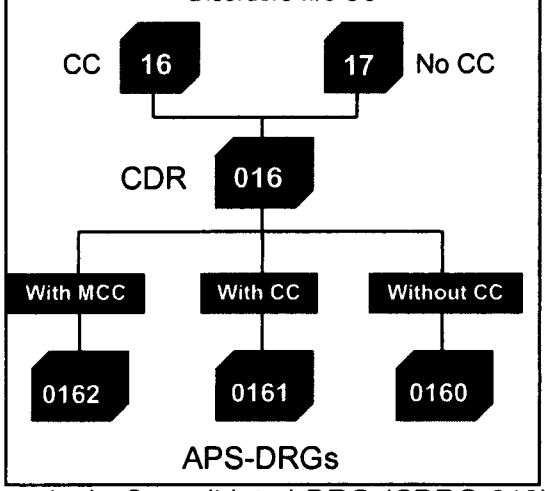
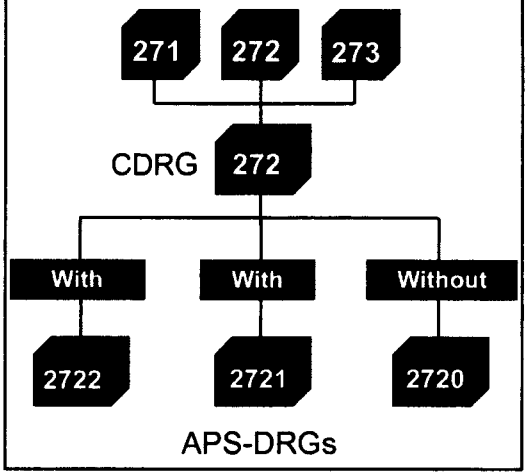


Figure 3-2 illustrates a situation in which the Medicare DRG system contains a pair of DRGs that are split based upon the presence or absence of a CC. DRG 16 contains cases with Non-Specific Cerebrovascular Disorders with CCs and DRG 17 represents cases with Non-Specific Cerebrovascular Disorders without CCs. Under the APS-DRG system, these two Medicare DRGs are combined into a single Consolidated DRG (CDRG 016). This CDRG is, in turn, subdivided into three distinct severity classes: Non-Specific Cerebrovascular Disorders with a Major CC (APS-DRG 0162), Non-Specific Cerebrovascular Disorders with a CC (APS-DRG 0161) and Non-Specific Cerebrovascular Disorders without a CC or an MCC (APS-DRG 0160). As a general rule, CDRGs are referenced either by the single Medicare DRG with which it is associated or by the "CC-DRG" if more than one DRG contributes to the CDRG.

Figure 3-3 illustrates a third possibility in the construction of CDRGs in the APS-DRG system. Here DRG 271, Skin Ulcers, is combined with the DRG pair, 272 and 273, for Major Skin Disorders with and without CCs to form a single consolidated DRG (272) for Major Skin Disorders. As in the previous examples, this CDRG is then split into three terminal categories based on their level of severity: Major Skin Disorders with a Major CC (APS-DRG 2722), Major Skin Disorders with a CC (APS-DRG 2721) and Major Skin Disorders without a CC or an MCC (APS-DRG 2720).

Figure 3-3
Medicare DRGs
271 – Skin Ulcers
272 – Major Skin Disorders w CC
273 – Major Skin Disorders w/o CC



4.3 Additional Enhancements of APS-DRGs

The CMS SDRG model did not specifically deal with newborns and neonates. Although these patients represent a major segment of the all-payer hospital population, they do not routinely occur in the Medicare experience. The APS-DRG model directly addresses this issue by revamping the current CMS newborn and neonate model (MDC 15). The APS-DRGs model defines sets of patient classes which are based on a combination of birthweight and diagnosis. Birthweight has been shown to be the strongest predictor of resource consumption and severity for newborns and neonates.

In addition, the APS-DRGs model goes beyond the SDRG model in its handling of CC exclusion logic, i.e. the exception logic which considers and accounts for the relationship between a patient's principal diagnosis and secondary diagnoses when evaluating severity class assignment. The APS-DRGs support Major CC exclusion logic, as well as MDC and DRG-specific severity class exclusions.

APS-DRGs result in a larger number of terminal categories than the underlying CMS DRG system. In the version 23, APS-DRGs have a total of 1,154 cells, while the CMS DRGs contain 526. However, the expansion in the number of categories enables the methodology to deliver a powerful, uniform and clinically-based methodology for refining Medicare DRGs on the basis of severity. Despite the larger number of cells than CMS DRGs, Ingenix research has shown that APS-DRGs yield weights that are stable for the vast majority of discharges when weights are estimated from the types of large databases that are typically used for such purposes, e.g., the annual MedPAR file or the National Inpatient Sample developed by the Agency for Healthcare Research and Quality. Where stability or small cell sizes are an issue, Ingenix has developed methods for imputing weights based on Bayesian statistical techniques.

5 Medicare-Modified Severity-Adjusted DRGS

Ingenix believes that the APS-DRG system represents a viable alternative to the CMS proposal for Consolidated Severity-adjusted DRGs. Because APS-DRGs are based on 23 years of experience with Medicare prospective payment and are designed to be a direct extension and enhancement of the current CMS DRG system, we believe a proposal to implement some form of APS-DRGs could quickly gain industry acceptance. The structure of the APS-DRG model is simple, explicit, and easily understood. The relationship between APS-DRGs and CMS DRGs means that providers will require relatively little retraining and that implementation of APS-DRGs should have limited impact on coder productivity. APS-DRGs can also be adapted easily to other DRG-based prospective payment systems, including Medicare reimbursement of long-term acute care hospitals and inpatient psychiatric facilities.

By incorporating a uniform clinical structure to represent levels of severity, APS-DRGs are able to achieve substantial improvements over CMS DRGs in statistical performance without sacrificing clinical coherence or the face validity of the model. APS-DRGs can be adapted to a wide variety of applications where a severity-adjustment methodology is necessary, including CMS quality initiatives, pay-for-performance, and the public release of severity-adjusted performance measures. Finally, CMS can implement APS-DRGs with almost no development effort on its part.

At the same time, we recognize that there are limitations to APS-DRGs as a methodology for use in reimbursing hospitals for inpatient services provided to Medicare beneficiaries. First, because it is an all-payer system, APS-DRGs are more granular and complicated than is really necessary for a Medicare-only methodology. As a result, a number of terminal categories are either empty or extremely sparse when evaluated in the context of Medicare discharge data. The relatively large number of cells in the APS-DRGs system contributes to this problem, meaning that cell-specific weights are not estimated as precisely as CMS might like for the Medicare system.

In addition, APS-DRGs only represent a partial solution to the fundamental problem that CMS is attempting to address with its proposal for Consolidated Severity-adjusted DRGs, i.e., relatively wide and systematic variations in within-cell variations in resource use that are predictably based on a patient's clinical characteristics. As a result, providers are able to "cherry-pick" patients by selecting those that they believe will have smaller resource requirements than the norm for a particular casemix category. APS-DRGs improve upon CMS DRGs in discouraging such behavior because they distinguish among CCs in terms of severity and because they isolate cases where expected resource requirements are especially high (or low) for a particular CDRG. Furthermore, because they apply the clinical severity-adjustment model consistently to all CDRGs, APS-DRGs are more vigorous than CMS DRGs in controlling for severity-differences. However, the APS-DRG system only uses the most significant secondary diagnosis to determine the severity-level that a case is assigned to within a CDRG. As it is currently designed, the APS-DRG algorithm identifies, but ignores, other coexisting clinical conditions that are comparable or less significant from a resource perspective.

For these reasons, Ingenix recommends that CMS implement a modified version of the APS-DRGs. The proposed modifications, which are described in more detail below, combine two basic enhancements. One is a systematic review of CDRGs with the goal

of reducing the number of CDRGs based on patterns of Medicare hospitalization. The other is a case-specific weighting system that explicitly controls for multiple coexisting clinical conditions among hospitalized patients.

5.1 Medicare Modifications to the APS-DRGs System

The current system of APS-DRGs contains a total of 386 Consolidated DRGs. Many of these involve patients who rarely appear in Medicare claims data. Others reflect distinctions that CMS has historically maintained in its DRG system that do not appear to be clinically and financially significant once severity-levels are taken into account.[6] For these reasons, Ingenix recommends that CMS consider a number of modifications to the current set of CDRGs before it adopts APS-DRGs for payment purposes.

The first recommended modification is to eliminate pediatric splits. There are currently 42 CDRGs that apply only to non-neonatal discharges under the age of 18. These pediatric CDRGs reflect the use of age splits in the underlying CMS DRG system but very few Medicare patients actually fall into these categories. These CDRGs can be eliminated without any appreciable deterioration in the clinical or financial performance of the system. To the extent that pediatric cases are systematically different, either clinically or financially, from the adult cases in the CDRGs to which they are subsequently assigned, the differences can be managed through adjustment to case-specific weights as discussed in the following section of the comment.

The second recommended modification is to remove the APS-DRG neonatal model from the system and to replace it with the current set of seven CMS DRGs in MDC 15. Since neonates are virtually non-existent in the Medicare system, the choice of a casemix classification model for them is substantively immaterial. Rather than create an artificial impediment to the adoption of a system for severity-adjusting DRGs by incorporating into the proposal a new neonatal model, we believe it is judicious to retain the current CMS model for MDC 15. This recommendation reduces the number of terminal categories in MDC 15 from 21 to 7.

The third recommended modification is to review the remaining CDRGs to identify opportunities for further aggregation. Such opportunities will appear in one of two forms. In some instances, the number of cases assigned to a CDRG will be so small that it does not seem reasonable to maintain the CDRG as a separate category. Under these circumstances, the CDRG in question can often be combined with another CDRG that is similar in terms of both clinical attributes and resource requirements. It may also make sense to incorporate the CDRG into the "other disorders" or "other procedures" CDRG that corresponds to its MDC. Opportunities for aggregating CDRGs go beyond sparse cells, however. We believe that a thorough analysis of CDRGs will identify additional

[6] Under the current Medicare system, two clinically similar DRGs can have substantially different weights either because they involve different treatment costs or because they have different distributions of clinical conditions that are not used for DRG assignment. For example, assume that two clinically-related DRGs have exactly the same expected resource requirements on a severity-adjusted basis, but that one DRG (e.g. DRG A) tends to have more cases in which patients have coexisting clinical conditions than the other DRG (DRG B). Under these circumstances, DRG A will ***appear*** to be a more serious and resource-intensive DRG than DRG B. Once severity-adjustment is introduced into the methodology, the apparent differences between the two DRGs will disappear. It is then possible and appropriate to combine DRGs A and B into a single consolidated DRG without any loss of performance in the system.

opportunities where two CDRGs are clinically similar and indistinguishable in terms of their resource requirements. We refer to these opportunities below as "Empirically Motivated Aggregations."

Ingenix has already conducted the type of review recommended above. The results of that review are summarized in Appendix I, which contains a list of 65 CDRGs that can reasonably be eliminated from the current APS-DRG system when the system is adapted to Medicare claims. Many of these CDRGs involve conditions that are rarely treated on an inpatient basis anymore, e.g., carpal tunnel syndrome. Others simply occur infrequently among Medicare beneficiaries. Table 4 shows the impact of these proposals on the number of CDRGs and terminal categories in the system.

Table 4.

	No. of CDRGs	**No. of Terminal Categories**
APS-DRGs v23.0	386	1154
less: Pediatric Splits	42	126
Net of Pediatric Modifications	344	1028
less: Neonatal Model	0	14
Net of Neonatal Modifications	344	1014
less: Empirically Motivated Aggregations	23	69
Net of All Proposed Modifications	321	945

There is one final set of aggregations that CMS may want to consider as part of its implementation of APS-DRGs. As is also true of the APR-DRGs upon which the proposed system of Consolidated Severity-adjusted DRGs is based, APS-DRGs sometimes produce one or more severity classes within a CDRG that are relatively sparse. These situations tend to generate weights that are not monotonic; i.e., weights that do not consistently increase with higher levels of severity. Non-monotonic weights are more of a statistical problem than a substantive concern, but they can create questions about the validity of the methodology for individuals who don't fully understand the nuances of statistical estimation. At least partly for this reason, CMS combined adjacent severity levels in developing its SDRG and CSA DRG proposals.

Ultimately, the decision to aggregate severity-levels that are either sparse or characterized by non-monotonic weights is a policy decision that CMS will have to make. Ingenix has historically refrained from aggregating severity-levels in its APS-DRGs system because we believe that the conceptual advantages of a uniform clinical model outweigh the difficulties created by sparse cells and occasionally non-monotonic weights. However, given the fact that CMS has twice opted to aggregate across severity levels and that aggregation undoubtedly leads to more stable weights over time, we have chosen to perform such aggregations in the empirical portion of the work described in this comment. These aggregations, which are summarized in Appendix II, had the effect of eliminating an additional 70 terminal categories for a total of 321 CDRGs and 875 terminal, severity-adjusted categories in our proposed MM APS-DRGs system.

5.2 Case-Specific Weights

As noted earlier, the fundamental problem that CMS is attempting to address with its proposal for a system of Consolidated Severity-adjusted DRGs is the fact that each terminal category in the current DRG system contains discharges with a variety of coexisting clinical conditions. By using a casemix classification that examines the full set of secondary diagnoses and assigns severity levels based upon combinations of secondary diagnoses (and other variables), we believe that CMS intends to improve upon the current DRG system and reduce the ability of providers to cherry-pick among Medicare admissions.

Ingenix recommends that CMS address this issue more directly by decomposing the problem of determining expected resource requirements into two components. The first is the resources required to treat patients assigned to each casemix category, assuming a "baseline" patient with no coexisting clinical conditions. The second component measures the extent to which coexisting clinical conditions justify an adjustment to the expectation associated with this baseline patient.

It is possible to conceive of a variety of strategies to operationalize this decomposition. Ingenix recommends that CMS adopt a simple, straightforward approach. Given the limitations of the ICD-9-CM coding system and current industry practices that affect the coding of secondary diagnoses, an elaborate logical construct for determining severity levels based on secondary diagnoses has little compelling justification. Instead, we recommend that CMS consider a simple count of independent coexisting conditions associated with any individual hospital stay. This approach was studied by Forthman et al. (2005) and found to be substantially superior to APR-DRGs in an independent study of APS-DRGs as a severity-adjustment methodology.

Historically, the inlier reimbursement amount associated with any individual discharge (R_i) has been based on a simple "base rate times weight" calculation:

$$R_i = W_i * CF$$

where W_i represents the DRG weight attached to discharge *i* and CF represents the conversion factor for the hospital in question.

The Ingenix proposal creates case-specific weights by adjusting the initial baseline weight based on two additional factors. One counts the number of *independent* coexisting clinical conditions that correspond to CCs in the APS-DRG system. The other counts the number of *independent* coexisting clinical conditions that correspond to Major CCs. Denoting these two variables as NCC_i and $NMCC_i$, respectively, inlier reimbursement would then be calculated as:

$$R_i = W_i * (1 + \beta1*NCC_i + \beta2*NMCC_i) * CF$$

where $\beta1$ and $\beta2$ represent adjustment factors associated with NCC_i and $NMCC_i$, respectively. $\beta1$ represents the average percent impact of an independent coexisting clinical condition on expected resource requirements; $\beta2$ represents the average percent impact of an independent major coexisting clinical condition. Ingenix has examined a number of specifications, but we believe that a model in which $\beta1$ and $\beta2$ are allowed to

vary by medical/surgical split within MDC is a reasonable compromise between flexibility and statistical precision in the estimation process.[7]

Our proposal does not envision simply counting the number of secondary diagnoses that are either CCs or Major CCs under the APS-DRG system. The reason for this is that secondary diagnoses are not necessarily independent of each other. Under the APS-DRG methodology, a secondary diagnosis is only considered to be a CC or a Major CC if the diagnosis generally has the effect of a CC or Major CC on expected resource use and if the diagnosis is independent of the rules used to assign a case to a specific CDRG. APS-DRGs evaluate the independence of secondary diagnoses at three levels: principal diagnosis, CDRG and MDC. Medicare Modified APS-DRGs extend this logic by:

- First, applying the basic APS-DRG exclusion logic for each of the secondary diagnoses,
- Then, establishing a hierarchy among secondary diagnoses that are considered to be CCs or Major CCs after the initial application of exclusion logic, and
- Finally, evaluating each secondary diagnosis against other secondary diagnoses that are higher in the hierarchy to ensure that they are independent.

The net effect is to reduce the entire set of secondary diagnoses associated with a discharge to a subset of coexisting clinical conditions that are independent of each other and that contribute to the expected resource requirements associated with patient care.

Two other aspects of our proposal merit further discussion. One involves the nature of the current CC and Major CC lists themselves. These lists were initially developed on the basis of the SDRG research conducted by CMS. HSS has maintained and updated those lists over time, but the emphasis of those updates has been to remain materially consistent with the CMS DRGs by incorporating regulatory changes and updates to the ICD-9-CM diagnosis coding system. As is the case with the current CMS DRGs, a thorough clinical and statistical review of these CC lists is undoubtedly warranted.

The second aspect of our proposal that could create some concern for CMS is the fact that adjusting case-specific weights with simple count variables creates the prospect of potentially unlimited adjustments to the weights. In theory, the number of potential adjustments is equal to the number of diagnoses considered for grouping minus two, one for the principal diagnosis and one for the CC or MCC that determines the severity class. If the number diagnoses considered for grouping is either very large or limitless, it creates an incentive for coders to scour the medical record for every coexisting clinical condition that can possibly be included on the bill and to query physicians relentlessly to support more aggressive coding.[8] Ingenix believes there are two strategies that can be

[7] This approach is similar to the strategy used by the Medicare prospective payment system for inpatient psychiatric facilities, which adjust DRG weights for specific comorbidities, age, and length of stay. It is also possible to re-interpret long-standing adjustments for indirect medical education and disproportionate share in the same way, i.e., adjustment to DRG-specific weights.

[8] The same criticism is actually a more significant problem for the proposed CSA DRG system because the underlying APR-DRG system is not sufficiently transparent that providers understand how specific codes affect the classification of cases. Absent such transparency, uncertainty about the role of individual codes, causes coders to code expansively and to query

used to address this issue. One option combines limits on the number of codes that will be considered for casemix classification purposes with a transparent methodology, so that coders know how individual codes affect assignment. Our analysis of the 2004 MedPAR file shows, for example, that more than 99 percent of cases contain no more than five (5) independent CCs and two (2) independent Major CCs, in addition to diagnoses that affect the initial assignment of a case to an APS-DRG. Relatively modest limits on the number of diagnoses would limit the potential for "infinite CCs" without seriously compromising the statistical performance of the system. These limits can be adjusted on an annual basis to continuously improve the system.

The other option is to convert the simple count variables described above into a series of categorical variables, each with a separate adjustment factor. This approach, which was embraced by Forthman et al. (2005), might decompose the CC count variable into a series of variables such as (1) Zero CCs, (2) 1-2 CCs, (3) 3-5 CCs, (4) 6+ CCs. Ingenix is prepared to analyze both approaches for CMS, but we believe that simply limiting the number of CCs and Major CCs that are "counted" is a more appropriate strategy to limit CMS' risk because it provides more consistent coding and billing incentives at the margin. Categorical variables will also require CMS to estimate more parameters, complicate the methodology, and make the system more difficult to explain and understand.

6 Empirical Analysis

The results presented earlier in Section 2 are taken from an analysis of the Ingenix proposal described above in the context of the 2004 MedPAR file. The analysis focused on the 11,935,330 discharges in the MedPAR 2004 file that were paid under the Medicare hospital inpatient DRG-based prospective payment system. It excludes discharges paid under other methodologies, such as discharges from Maryland hospital, discharges from long-term acute care hospitals, and discharges from distinct part units and critical access facilities. 116 of these cases were grouped into DRGs 469 or 470, leaving a total of 11,935,214 discharges available for this analysis. Each case was then grouped into the version 22 CMS DRGs, the version of the DRGs that was available on the file, to validate the casemix classification process and to determine if age was a factor that needed to be taken into account in a final classification process. Each discharge was then classified into the v23.0 APS-DRGs and the "Medicare-Modified APS-DRGs" that were described above and that incorporates CDRG and within-CDRG severity-level aggregations as well as the logic for scoring coexisting clinical conditions.

6.1 Distribution of CCs and Major CCs

Table 5 below summarizes the cross-frequency of the two count variables described above, NCC and NMCC, within the MedPAR data. Because MedPAR contains a maximum of nine (9) diagnoses, the maximum number of independent coexisting conditions not used to classify a case into a terminal category is seven (7). The first diagnosis is always the principal and one other diagnosis will be used to determine a CC or Major CC severity level in the classification system if there is at least one CC or Major CC on the record. Consequently, the sum of NCC and NMCC cannot exceed seven (7).

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physicians frequently. This is certainly the case in Maryland, where individual hospitals report substantial reductions in coder productivity.

Table 5.

No. of Ind. "Unused" MCCs (NMCCs)	Number of Independent "Unused" CCs (NCCs)								Row Total
	0	1	2	3	4	5	6	7	
0	60.7%	17.1%	9.2%	4.6%	2.2%	1.0%	0.4%	0.1%	95.39%
1	0.2%	0.5%	0.7%	0.7%	0.6%	0.3%	0.1%	-	3.10%
2	0.0%	0.1%	0.2%	0.3%	0.3%	0.1%	-	-	1.07%
3	0.0%	0.0%	0.1%	0.1%	0.1%	-	-	-	0.34%
4	0.0%	0.0%	0.0%	0.0%	-	-	-	-	0.08%
5	0.0%	0.0%	0.0%	-	-	-	-	-	0.01%
6	0.0%	0.0%	-	-	-	-	-	-	0.00%
7	0.0%	-	-	-	-	-	-	-	0.00%
Column Total	60.9%	17.8%	10.3%	5.9%	3.2%	1.5%	0.5%	0.1%	100.00%

According to Table 5, more than 60 percent of the cases in MedPAR contain no unused independent CCs or MCCs. While nearly 39 percent of cases contain one or more unused CCs, fewer than five percent contain any unused MCCs. It is also interesting to note that the number of unused CCs is not independent of the number of unused MCCs. That is, as the number of unused CCs increases, the proportion of cases with one or more unused MCCs also increases.

These results suggest two important conclusions. First, MedPAR appears to contain enough data to support estimation of baseline weights for most APS-DRG terminal categories by restricting the estimation process to situations where NCC=NMCC=0. Second, reasonable restrictions on the number of independent CCs and Major CCs appear to be a practical solution to the problem of potentially unlimited numbers of coexisting conditions entering into the weight adjustment process described above. 99 percent of the discharges in MedPAR contain five or fewer unused CCs and no more than 2 unused MCCs.

If CMS adopts the Ingenix proposal, it seems likely that hospitals will respond to the new incentives created by the system and increase the number of CCs and MCCs that appear in these data. However, it is unclear at present if these increases would require CMS to increase the number of CCs or MCCs that it recognized in the weight adjustment process.

6.2 Unadjusted Expected Values

The next step in our empirical analysis was to develop expected values for each case in the MedPAR data base using three separate classification methodologies: CMS DRGs v22.0, CSA DRGs, and MM APS-DRGs. Two different types of weights have been used in prospective payment systems, charge and cost-based weights. Given the relatively short period of time available to prepare a response to the April 25 NPRM, Ingenix elected to focus on charge-based weights. We also opted not to replicate the proposed HSRVcc methodology outlined by CMS in its proposed rule. Instead, we used a simpler weight-development process that we nevertheless believe is sufficient to illustrate our basic points.

The first step in our process for estimating expected values was to standardize the total charge reported on each claim in MedPAR by adjusting for labor market differences, indirect medical education (IME), and disproportionate share (DSH). Ingenix maintains a national data base of Medicare payment parameters which enables us to determine the wage index assigned to each Medicare participating hospital for any discharge date, as well as the IME and DSH adjustment factors used by Fiscal Intermediaries at any point in time. As discussed in the previous section, total charges on each claim were divided by the following expression:

$$[\,(1-S_h) + S_h * WAGE_h\,] * (\,1 + IMEADJ_h + DSHADJ_h\,)$$

where

S_h = the labor share associated with a hospital at a given point in time,
$WAGE_h$ = the hospital's wage index,
$IMEADJ_h$ = the hospital's IME adjustment for operating costs, and
$DSHADJ_h$ = the hospital's DSH adjustment for operating costs.

We then repeated the same core estimation procedure to develop estimated values for CMS DRGs and Consolidated Severity-adjusted DRGs. Specifically, for each terminal category, we first calculated the arithmetic mean and standard deviation of the natural logarithm of the standardized total charge. We then identified all cases where the natural logarithm of standardized total charge was more than three standard deviations from the mean of the log-transformed data. Excluding such cases, we then calculated the arithmetic mean of the standardized total charge among remaining observations for each terminal category to produce essentially a DRG-specific expected standardized total charge. These expected values were then normalized by the overall mean standardized total charge to produce DRG-specific weights. Appendix III contains the resulting means, standard deviations, coefficients of variation and weights for the CMS DRGs. Appendix IV contains the same statistics for the proposed system of Consolidated Severity-adjusted DRGs. Each of these expected values was merged back onto to MedPAR data for further analysis, as described below.

6.3 Case-Specific Expected Values

The parameters associated with the Medicare Modified APS-DRG system were then estimated using the methods described in Appendix VIII. In particular, we first estimated baseline expected values from a subset of MedPAR claims where NCC=NMCC=0, approximately 60 percent of the entire file. The calculation of these expected values followed the same methodology described above. We first trimmed the data at ±3 standard deviation from the arithmetic mean of the log-transformed data and then calculated the arithmetic mean of the remaining observations to determine a baseline expected value for each terminal category. For each discharge, we then calculated the percentage deviation of each actual value from its expected value. Percent deviations were then regressed on counts of the number of independent CCs and MCCs that are not used in classifying patients into the terminal categories, by MDC split into medical and surgical cases.

Given the baseline expected values and estimated adjustment factors, we then assigned expected values to each case in the MedPAR file, calculated the average expected value, and normalized the baseline expected values by dividing each by the overall

average expected value. The resulting case-specific weights, when adjusted by the estimated adjustment factors and actual NCC and NMCC values, have an overall average of one (1.0000). Appendix V contains means, standard deviations and other summary statistics, by Consolidated DRG (CDRG). Appendix VI contains a set of weights that were developed using the methodologies described above and a dependent variable that corresponds to a "standardized total charge."[9] Similarly, Appendix VII contains CC and MCC adjustment factors estimated by MDC and medical-surgical split.

7 Advantages of MM APS-DRGs to CMS

Medicare Modified APS-DRGs offer many advantages to CMS and they are demonstrably superior to the proposal for a system of Consolidated Severity-adjusted DRGs. First and most importantly, MM APS-DRGs offer a strong value proposition to CMS. They represent a substantial improvement over both CMS DRGs and CSA DRGs in their ability to distinguish among cases based on expected resource use. They do not use treatment decisions to determine severity, unlike CSA DRGs, but rely instead only on encoded information that describes the patient's underlying clinical condition. They enhance, rather than replace the current system of CMS DRGs that has served the Medicare program well for 23 years and are fully compatible with other CMS initiatives that require a sophisticated casemix classification system.

Medicare Modified APS-DRGs are a relatively straightforward enhancement to the current system of Medicare DRGs. The relative weight attached to any individual Medicare discharge will be assigned through the following seven (7)-step process:

1. Assign the case to a Consolidated DRG based on the criteria that parallel those currently used by Medicare DRGs, primarily the principal diagnosis (PDX) and the presence or absence of an operating room procedure.
2. Evaluate each secondary diagnosis and determine whether it represents a CC or a MCC.
3. Apply a standard set of exclusion logic to determine which CCs and MCCs, if any, are independent of the principal diagnosis.
4. Assign the case to a severity level based on the presence of an independent MCC (Severity Level 2), the presence of an independent CC (Severity Level 1), or the absence of an independent CC or MCC (Severity 0).
5. Apply exclusion logic iteratively to all secondary diagnoses that are independent of the PDX to identify CCs and MCCs that are independent of each other. Count the number of independent CCs (NCC) and Major CCs (NMCC) that are not used in the assignment of the case to a CDRG and a severity level.
6. Assign a baseline weight to the case based upon the CDRG and severity level with which it is associated.

[9] As discussed previously, the term "Standard Total Charge" refers to the total charge on the bill, adjusted by the appropriate wage index for each hospital and then divided by (1+IMEADJ+DSHADJ) where IMEADJ and DSHADJ are the operating indirect medical education and operating disproportionate share adjustments for each hospital, respectively.

7. Adjust the baseline weight based on the number of independent CCs (NCC) and MCCs (NMCC) using adjustment factors appropriate for the CDRG. These adjustment factors will generally vary, depending upon whether the case is a medical or surgical discharge and the MDC to which the case has been assigned.

In contrast, CSA DRGs require at least 18 steps based on a chart published in the NPRM.

MM APS-DRGs have a strong scientific foundation. Our proposal envisions a strategy that builds off of the current clinical content of CMS DRGs to ease the transition effort and anxiety, but will subsequently enhance that content to reflect additional functionality and explanatory power of the APS-DRG system. By determining severity on the basis of diagnostic information alone, our proposal remains neutral with respect to the choice of treatment decisions. At the same time, it provides strong incentives for providers to code cases completely and accurately and to deliver services as efficiently as possible.

More generally, the coding issues associated with our proposal will be less burdensome for the industry than with CSA DRGs. Under our proposal, every coder who chooses to learn the system will know exactly which codes are CCs or MCCs. For a given case, he or she will be also able to determine which CCs and MCCs represent independent coexisting clinical conditions that will affect reimbursement. As a result, MM APS-DRGs provide incentives to code cases completely but appropriately, given current coding guidelines. These incentives differ from those of CSA DRGs, where the lack of transparency encourages coders to code *every* secondary diagnosis that can be conceived of for a given case regardless of its clinical significance. The incentives also differ from those of the current CMS DRGs, where coders face different incentives that depend upon the presence or absence of a CC-split in the potential DRGs for a case. By providing a consistent set of transparent incentives to code clinically appropriate conditions, MM APS-DRGs will improve the information available to CMS for future DRG development and generally promote sound coding practices regardless of the specific set of CDRGs that are currently defined for reimbursement purposes.

We also believe that our proposal will be much better received within the industry than the proposal for CSA DRGs precisely because of its simplicity and transparency. MM APS-DRGs will not require significant new training on the part of HIM professionals. Because they represent a relatively simple extension of the current CMS DRGs, MM APS-DRGs can also be implemented with relatively little expense or increase in administrative burden. Coders will know exactly how severity levels are determined and what factors will cause the reimbursement on a case to change. Given this transparency, MM APS-DRGs will enable CMS to continue its important commitment to an open process for maintaining and updating its casemix classification system over time.

MM APS-DRGs outperform CSA DRGs in their ability to explain variations across individual cases in the resources required for treatment. In addition, MM APS-DRGs only use secondary diagnoses to measure severity. Unlike CSA DRGs, they do not create financial incentives that could compromise clinical decisions. In effect, MM APS-DRGs are statistically powerful in discriminating among patients based on their underlying clinical conditions but they remain neutral with respect to clinical decisions about the course of treatment.

The fact that CSA DRGs determine severity of illness in part based on how patients are treated rather than the clinical problems that they face is just one example of the clinical shortcomings of Consolidated Severity-adjusted DRGs and the APR-DRGs upon which they are based.

For example, APR-DRGs automatically "resequence" diagnoses for casemix classification purposes without regard to the underlying clinical documentation that may have caused a coder to select a principal diagnosis. For example, consider a patient with chest pain who is seen in the emergency department and admitted to the hospital to rule out myocardial infarction because of prior cardiac history. Suppose that this patient had a recent cardiac catheterization that showed evidence of coronary artery disease (CAD), but that the CAD was not significant enough for treatment or to be causing the chest pain. As a result, the attending physician documents the final principal diagnosis as "non-cardiac chest pain" (786.59) and indicates a secondary diagnosis of CAD (414.01). The current CMS DRGs will assign this case to DRG 143 ("Chest Pain"). However, the APR-DRGs will automatically treat the CAD as the principal diagnosis because its logic presumes that any case with chest pain and a secondary diagnosis of coronary artery disease or angina should be classified to the coronary artery disease/angina APR-DRG. The case described above, then will be grouped into "Angina Pectoris and Coronary Atherosclerosis SOI 1."

Another example is the fact that APR-DRGs fail to recognize bilateral procedures. Suppose a patient with degenerative joint disease of both knees (PDX of 715.96) is admitted to a hospital for a bilateral knee replacement. Under current coding guidelines, the bilateral procedure is coded by assigning procedure code 81.54 twice. The current CMS DRG system will group the bilateral procedure into DRG 471 or 472 ("Bilateral or Multiple Major Joint Procedure, Lower Extremity, with or without CC"). APR-DRGs ignore the second procedure code and group the case into APR-DRG 302 ("Knee Joint Replacement"). This means that the hospital receives no additional payment for the second knee replacement, which means in all likelihood that each knee will be treated during separate hospital stays even when a bilateral procedure might be more efficient and clinically appropriate. Note that this will also cause Medicare to overpay for single knee replacements, since the weight attached to the knee replacement CSA DRG will represent some weighted average of the costs associated with single and bilateral procedures.

APR-DRGs also contain numerous examples of situations in which they encourage coding that is inconsistent with current coding guidelines to affect severity levels. Consider the following examples:

1) A patient is admitted to the hospital with gallstones (cholelithiasis) and acute cholecystitis. Coding guidelines call for the assignment of combination code 574.00 ("Calculus of gallbladder with acute cholecystitis"). However, coders can increase the severity level in APR-DRGs by assigning a separate secondary diagnosis of acute cholecystitis (575.0) even though it is subsumed into the principal diagnosis code. This same inappropriate increase in severity occurs when a procedure such as a cholecystectomy is performed.

2) A patient is admitted with an incisional hernia that was found to be obstructed. Combination code 552.21 ("Incisional hernia with

obstruction") includes both conditions. However, coders can increase the severity level in APR-DRGs by assigning a separate secondary diagnosis for bowel obstruction 560.89 ("Intestinal obstruction NEC"). Again, APR-DRGs reward coders for assigning components codes in violation of current coding guidelines.

3) A patient is admitted to the hospital with a fracture of the lower leg that is also dislocated. According to *Coding Clinic*, (3rd Quarter 1990), "[f]or purposes of classification, ICD-9-CM assigns only the fracture code to fracture-dislocation of the same site...[and]...it is incorrect to also code the dislocation." However, APR-DRGs will increase the SOI level assigned to a case if the coder includes a secondary diagnosis indicating the dislocation.

According to 3M's documentation, the first step in the first phase of assigning an APR-DRG is to "eliminate secondary diagnoses that are associated with the principal diagnosis." That does not happen in these three examples. It is virtually impossible to determine the full scope of problems like these due to the lack of transparency in the system. CMS and 3M have yet to disclose sufficient details about the methodology to facilitate a systematic and through review.

It is also clear that CSA DRGs will cause coders to code excessively, and potentially assign codes in contravention of current coding guidelines. At best, the incentives of the system will drive up the casemix index across the industry to an extent that probably cannot be predicted or controlled by CMS at present. At worst, these incentives will create a host of new compliance issues that will need to be addressed by individual hospitals, CMS, and the Office of the Inspector General.

Ingenix does not mean to suggest that Medicare Modified APS-DRGs or the CMS DRGs upon which they are based do not contain clinically inappropriate incentives or rules that contravene established coding guidelines. They do. However, we believe that it is better to work with and modify a system with known flaws based on 23 years of experience rather than replace it with a system with which most coders have little experience and whose most important deficiencies are yet to be discovered. We also believe that it is essential to make any severity-adjustment system transparent to the industry to facilitate the kind of public debate that will enable CMS to identify, evaluate and remedy the types of problems described above. Ingenix is fully prepared to subject its methodology to systematic and rigorous scrutiny through public debate. This is precisely the level of review that is currently not possible with the CMS proposal for Consolidated Severity-adjusted DRGs.

APPENDICES

Appendix I –CDRG Aggregations Proposed by INGENIX Under MM APS-DRGs

Appendix II –Aggregations of Severity-Levels Proposed by INGENIX

Appendix III – Summary Statistics for CMS DRGs (v22.0)

Appendix IV – Summary Statistics for Consolidated Severity-adjusted DRGs

Appendix V – Summary Statistics for Medicare Modified APS-DRGs

Appendix VI – Mean Standardized Total Charge and Base Weights for Medicare Modified APS-DRGs

Appendix VII – Estimated Case-Specific Weight Adjustment Factors for MM APS-DRGs

Appendix VIII – Estimation Procedures

CDRG Aggregations Proposed by INGENIX Under Medicare Modified APS-DRGs

Original CDRG	CDRG Label	Medicare Modified CDRG	Revised Label
001	CRANIOTOMY AGE >17	001	CRANIOTOMY
003	CRANIOTOMY AGE 0-17		
024	SEIZURE & HEADACHE AGE >17	024	SEIZURE & HEADACHE
026	SEIZURE & HEADACHE AGE 0-17		
028	TRAUM STUPOR&COMA,COMA<1HR,AGE>17	028	TRAUM STUPOR&COMA,COMA<1 HR
030	TRAUM STUPOR & COMA<1 HR, AGE 0-17		
031	CONCUSSION AGE >17	031	CONCUSSION
033	CONCUSSION AGE 0-17		
038	PRIMARY IRIS PROCEDURES	039	PRIMARY IRIS & LENS PROCEDURES
039	LENS PROCS WITH OR WO VITRECTOMY		
040	EXTRAOCLR PROCS EXC ORBIT AGE >17	040	EXTRAOCLR PROCS EXC ORBIT
041	EXTRAOCLR PROCS EXC ORBIT AGE 0-17		
046	OTHER DISORDERS OF EYE AGE >17	046	OTHER DISORDERS OF EYE
048	OTHER DISORDERS OF EYE AGE 0-17		
053	SINUS & MASTOID PROCS AGE>17	053	SINUS & MASTOID PROCS
054	SINUS & MASTOID PROCS AGE 0-17		
056	MISC EAR,NOSE,MOUTH& THROAT PROCS	056	MISC EAR,NOSE,MOUTH& THROAT PROCS
057	T&A EX TNSLCT/ADNDCT ONLY AGE >17		
058	T&A EX TNSLCT/ADNDCT ONLY AGE 0-17		
059	TONSLCT OR ADENOIDCT ONLY AGE >17		
060	TONSLCT OR ADENOIDCT ONLY AGE 0-17		
061	MYRINGOTOMY W TUBE INSERT AGE >17	061	MYRINGOTOMY W TUBE INSERT
062	MYRINGOTOMY W TUBE INSERT AGE 0-17		
066	EPISTAXIS	066	EPISTAXIS & EPIGLOTTITIS
067	EPIGLOTTITIS		
068	OTITIS MEDIA & URI AGE >17	068	OTITIS MEDIA & URI
070	OTITIS MEDIA & URI AGE 0-17		
071	LARYNGOTRACHEITIS	073	OTH EAR,NOSE,MOUTH,THROAT DISORDERS
073	OTH EAR,NOSE,MOUTH,THROAT AGE >17		
074	OTH EAR,NOSE,MOUTH,THROAT DX 0-17		
079	RESP INFECT & INFLAM AGE >17	079	RESP INFECT & INFLAM
081	RESP INFECT & INFLAM AGE 0-17		
089	SIMP PNEU,PLRSY,INSTIT DIS AGE>17	089	SIMP PNEU,PLRSY,INSTIT DIS
091	SIMP PNEU,PLRSY,INSTIT DIS 0-17		

CDRG Aggregations Proposed by INGENIX Under Medicare Modified APS-DRGs

Original CDRG	CDRG Label	Medicare Modified CDRG	Revised Label
096	BRONCHITIS & ASTHMA AGE >17	096	BRONCHITIS & ASTHMA
098	BRONCHITIS & ASTHMA AGE 0-17		
119	VEIN LIGATION & STRIPPING	120	OTHER CIRCULATORY SYST O.R. PROCS
120	OTHER CIRCULATORY SYST O.R. PROCS		
135	CARD CONGEN & VALV DISOR AGE >17	135	CARD CONGEN & VALV DISOR
137	CARD CONGEN & VALV DISOR AGE 0-17		
154	STOMACH,ESOPH & DUOD PROC AGE >17	154	STOMACH,ESOPH & DUOD PROC
156	STOMACH,ESOPH & DUOD PROC AGE 0-17		
159	HERNIA PROC EXC ING,FEMOR AGE >17	159	HERNIA PROC EXC ING,FEMOR
161	ING & FEMORAL HERNIA PROC AGE >17	161	ING & FEMORAL HERNIA PROC
163	HERNIA PROCEDURES AGE 0-17		
182	ESPHGITIS,GE,MISC DIG DIS AGE >17	182	ESPHGITIS,GE,MISC DIG DIS
184	ESPHGITIS,GE,MISC DIG DIS AGE 0-17		
185	DENTAL & ORAL DISORDERS AGE >17	186	DENTAL & ORAL DISORDERS
186	DENTAL & ORAL DISORDERS AGE 0-17		
188	OTHER DIGESTIVE SYSTEM DX AGE >17	188	OTHER DIGESTIVE SYSTEM DX
190	OTHER DIGESTIVE SYSTEM DX AGE 0-17		
193	BIL PROC,EX ONLY CHLCYST W/WO CDE	193	BIL PROC, EX ONLY CHLCYST WO CDE
195	CHOLECYSTECTOMY W CDE		
210	HIP&FEMUR PROC,EX MAJ JNT,AGE >17	210	HIP&FEMUR PROC, EX MAJ JNT
212	HIP&FEMUR PROC,EX MAJ JNT,AGE 0-17		
218	LW EXT&HUM PROC,EX HIP,FT,FEM >17	218	LW EXT&HUM PROC,EX HIP,FT,FEM
220	LW EXT&HUM PROC,EX HIP,FT,FEM 0-17		
253	FX,SPR,STR,DSL UP EXT,LOW LEG >17	253	FX,SPR,STR,DSL UP EXT,LOW LEG
255	FX,SPR,STR,DSL UP EXT,LOW LEG 0-17		
277	CELLULITIS AGE >17	277	CELLULITIS
279	CELLULITIS AGE 0-17		
280	TRAUMA SKN,SUBCUT TISS&BREAST >17	280	TRAUMA SKN,SUBCUT TISS & BREAST
282	TRAUMA SKN,SUBCUT TISS&BREAST 0-17		
290	THYROID PROCEDURES	290	THYROID & THYROGLOSSAL PROCS
291	THYROGLOSSAL PROCEDURES		
312	URETHRAL PROCEDURES, AGE >17	312	URETHRAL PROCEDURES
314	URETHRAL PROCEDURES, AGE 0-17		
316	RENAL FAILURE	316	ADMIT FOR RENAL DIALYSIS OR FAILURE
317	ADMIT FOR RENAL DIALYSIS		

CDRG Aggregations Proposed by INGENIX Under Medicare Modified APS-DRGs

Original CDRG	CDRG Label	Medicare Modified CDRG	Revised Label
320	KIDNEY,URIN TRACT INFECT AGE >17	320	KIDNEY,URIN TRACT INFECT
322	KIDNEY,URIN TRACT INFECT AGE 0-17		
325	KIDNY,URIN TRACT SIGN,SYMP AGE>17	325	KIDNY,URIN TRACT SIGN,SYMP
327	KIDNY,URIN TRACT SIGN,SYMP 0-17		
328	URETHRAL STRICTURE AGE >17	331	OTH KIDNEY & URINARY TRACT DX
330	URETHRAL STRICTURE AGE 0-17		
331	OTH KIDNEY & URIN TRACT DX AGE>17		
333	OTH KIDNEY & URIN TRACT DX 0-17		
339	TESTES PROCEDURES AGE >17	339	TESTES PROCEDURES
340	TESTES PROCEDURES AGE 0-17		
342	CIRCUMCISION AGE >17	342	CIRCUMCISION
343	CIRCUMCISION AGE 0-17		
350	INFLAMMATION OF MALE REPRO SYS	352	OTHER MALE REPRODUCTIVE SYSTEM DX
351	STERILIZATION, MALE		
352	OTHER MALE REPRODUCTIVE SYSTEM DX		
361	LAPAROSCPY& INCIS TUBAL INTERRUPT	361	TUBAL INTERRUPTION
362	ENDOSCOPIC TUBAL INTERRUPTION		
374	VAGINAL DELIVERY W STERIL &/OR D&C	374	VAGINAL DELIVERY W OR PROC
375	VAG DEL W O.R EX STERIL &/OR D&C		
379	THREATENED ABORTION	383	OTH ANTEPARTUM DX
380	ABORTION WO D&C		
382	FALSE LABOR		
383	OTH ANTEPARTUM DX W MED COMPLIC		
384	OTH ANTEPARTUM DX WO MED COMPLIC		
392	SPLENECTOMY AGE >17	392	SPLENECTOMY
393	SPLENECTOMY AGE 0-17		
395	RED BLOOD CELL DISORDERS AGE >17	395	RED BLOOD CELL DISORDERS
396	RED BLOOD CELL DISORDERS AGE 0-17		
405	ACUTE LEUKEMIA WO MAJ OR PROC 0-17	473	ACUTE LEUKEMIA WO MAJ OR PROC
473	ACU LEUKEM WO MAJ OR PROC AGE>17		
416	SEPTICEMIA AGE >17	416	SEPTICEMIA
417	SEPTICEMIA AGE 0-17		
419	FEVER OF UNKNOWN ORIGIN AGE >17	419	FEVER OF UNKNOWN ORIGIN
421	VIRAL ILLNESS AGE >17	421	VIRAL ILLNESS
422	VIRAL ILL&FEVER UNKNWN ORIG 0-17		

CDRG Aggregations Proposed by INGENIX Under Medicare Modified APS-DRGs

Original CDRG	CDRG Label	Medicare Modified CDRG	Revised Label
431	CHILDHOOD MENTAL DISORDERS	432	OTHER MENTAL DISORDER DIAGNOSES
432	OTHER MENTAL DISORDER DIAGNOSES		
444	TRAUMATIC INJURY AGE >17	444	TRAUMATIC INJURY
446	TRAUMATIC INJURY AGE 0-17		
447	ALLERGIC REACTIONS AGE >17	447	ALLERGIC REACTIONS
448	ALLERGIC REACTIONS AGE 0-17		
449	POISON&TOXIC EFFECTS DRUGS AGE>17	449	POISON & TOXIC EFFECTS, DRUGS
451	POISON&TOXIC EFFECTS DRUGS 0-17		
465	AFTERCARE	467	OTH FCTRS INFLUENCING HLTH STATUS
467	OTH FCTRS INFLUENCING HLTH STATUS		
504	EXT,FULL BURN W MV 96+H W SK GRFT	506	OTHER BURNS W OR PROC
506	FULL BRN W GR OR INHAL W SIG TR		
508	FULL BRN WO GR OR INHAL W SIG TR	510	OTHER BURNS WO OR PROC
509	FULL BRN WO GR OR INHAL WO SIG TR		
510	NON-EXT BURNS W SIG TRAUMA		

AGGREGATIONS OF SEVERITY LEVELS PROPOSED BY INGENIX

CDRG	CDRG Description	Combined Severity Level		
		No CC	CC	MCC
039	PRIMARY IRIS & LENS PROCEDURES	X	X	
040	EXTRAOCLR PROCS EXC ORBIT	X	X	
042	INTRAOCULAR PROCS EXC IRIS & LENS	X	X	
045	NEUROLOGICAL EYE DISORDERS	X	X	
061	MYRINGOTOMY W TUBE INSERT	X	X	
087	PULMONARY EDEMA & RESP FAILURE	X	X	
201	OTH HEPATOBIL, PANCREAS O.R. PROC	X	X	
232	ARTHROSCOPY	X	X	
237	SPRN,STRN,DISLOC HIP,PELVIS,THIGH	X	X	
242	SEPTIC ARTHRITIS	X	X	
261	BRST PR NON-MAL,EX BIOP&LOC EXCIS	X	X	
262	BRST BIOP& LOC EXCIS FOR NON-MAL	X	X	
267	PERIANAL & PILONIDAL PROCEDURES	X	X	
274	MALIGNANT BREAST DISORDERS	X	X	
276	NON-MALIGNANT BREAST DISORDERS	X	X	
287	SKN GRFT,DBRD ENDO,NUTR,METB DIS	X	X	X
312	URETHRAL PROCEDURES	X	X	
323	URINARY STONES W ESW LITHOTRIPSY	X	X	
339	TESTES PROCEDURES	X	X	
341	PENIS PROCEDURES	X	X	
342	CIRCUMCISION	X	X	
344	OTH MALE REPRO SYS PROCS MALIG	X	X	
345	OTH MALE REPRO SYS PROCS EX MALIG	X	X	
361	TUBAL INTERRUPTION	X	X	
366	MALIGNANCY, FEMALE REPRO SYSTEM	X	X	
372	VAGINAL DELIVERY W COMPLIC DXS	X	X	
373	VAGINAL DELIVERY WO COMPLIC DXS	X	X	
374	VAGINAL DELIVERY W OR PROC	X	X	
376	POSTPART&POST ABORT DX WO OR PROC	X	X	
377	POSTPART&POST ABORT DX W OR PROC	X	X	
378	ECTOPIC PREGNANCY	X	X	
381	ABORTN W D&C,ASP CURETT,HYSTEROT	X	X	
408	MYEL DIS,PRLY DIF NEO&OTH OR PROC	X	X	
409	RADIOTHERAPY	X	X	
412	HISTORY OF MALIGNANCY	X	X	X
416	SEPTICEMIA	X	X	X
419	FEVER OF UNKNOWN ORIGIN	X	X	
424	O.R PROC W PRINC DX OF MENTAL ILL	X	X	
426	DEPRESSIVE NEUROSES	X	X	
427	NEUROSES EXCEPT DEPRESSIVE	X	X	
428	DISOR OF PERSONALTY&IMPULSE CNTRL	X	X	
432	OTHER MENTAL DISORDER DIAGNOSES	X	X	
439	SKIN GRAFTS FOR INJURIES	X	X	
441	HAND PROCEDURES FOR INJURIES	X	X	
462	REHABILITATION	X	X	
473	ACU LEUKEM WO MAJ OR PROC	X	X	
480	LIVER &/OR INTESTINAL TRANSPL	X	X	X
481	BONE MARROW TRANSPLANT	X	X	

AGGREGATIONS OF SEVERITY LEVELS PROPOSED BY INGENIX

CDRG	CDRG Description	Combined Severity Level		
		No CC	CC	MCC
488	HIV W EXTENSIVE O.R. PROCEDURE	X	X	X
495	LUNG TRANSPLANT	X	X	
505	EXT,FULL BURN W MV 96+H WO SK GRFT	X	X	
506	OTHER BURNS W OR PROC	X	X	
512	SIMULT PANCREAS/KIDNEY TRANSPLANT	X	X	
513	PANCREAS TRANSPLANT	X	X	
525	OTHER HEART ASSIST SYSTEM IMPLANT	X	X	X
535	CARD DEFIB W CATH W AMI/HF/SHOCK	X	X	X
536	CARD DEFIB W CATH WO AMI/HF/SHOCK	X	X	X
541	ECMO,TRCH MV96+/PDX EX FMN W MJ OR	X	X	X
542	TRACH MV96+/PDX EX FMN WO MAJ OR	X	X	X
546	SPNL FUSN EX CERV W CRV SPINE, MAL	X	X	

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
	Average Coefficient of Variation (Discharge Weighted) Across CMS DRGs					101.77
	ALL DISCHARGES COMBINED	11,935,206	22,887	35,524	1.00000	155.22
001	CRANIOTOMY AGE >17 W CC	22,844	52,509	47,267	2.29433	90.02
002	CRANIOTOMY AGE >17 W/O CC	10,247	30,723	20,314	1.34238	66.12
003	CRANIOTOMY AGE 0-17	4	69,129	81,811	3.02049	118.35
006	CARPAL TUNNEL RELEASE	403	12,325	11,225	0.53852	91.08
007	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W CC	15,387	40,728	47,481	1.77956	116.58
008	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC	3,676	23,703	17,024	1.03565	71.82
009	SPINAL DISORDERS & INJURIES	1,911	21,575	25,003	0.94267	115.89
010	NERVOUS SYSTEM NEOPLASMS W CC	19,121	18,797	19,126	0.82131	101.75
011	NERVOUS SYSTEM NEOPLASMS W/O CC	3,231	13,521	11,620	0.59079	85.94
012	DEGENERATIVE NERVOUS SYSTEM DISORDERS	53,258	13,799	17,544	0.60292	127.14
013	MULTIPLE SCLEROSIS & CEREBELLAR ATAXIA	7,204	13,353	16,938	0.58344	126.85
014	INTRACRANIAL HEMORRHAGE OR CEREBRAL INFARCTION	232,605	19,200	20,638	0.83891	107.49
015	NONSPECIFIC CVA & PRECEREBRAL OCCLUSION W/O INFARCT	74,753	14,422	14,439	0.63016	100.12
016	NONSPECIFIC CEREBROVASCULAR DISORDERS W CC	15,935	20,415	22,581	0.89203	110.61
017	NONSPECIFIC CEREBROVASCULAR DISORDERS W/O CC	2,984	11,346	9,141	0.49577	80.56
018	CRANIAL & PERIPHERAL NERVE DISORDERS W CC	32,520	15,438	17,632	0.67454	114.21
019	CRANIAL & PERIPHERAL NERVE DISORDERS W/O CC	8,432	11,200	11,759	0.48936	105.00
020	NERVOUS SYSTEM INFECTION EXCEPT VIRAL MENINGITIS	6,435	40,888	44,168	1.78657	108.02
021	VIRAL MENINGITIS	2,177	22,482	23,540	0.98234	104.71
022	HYPERTENSIVE ENCEPHALOPATHY	3,255	17,682	18,472	0.77259	104.47
023	NONTRAUMATIC STUPOR & COMA	10,623	12,171	13,173	0.53178	108.23
024	SEIZURE & HEADACHE AGE >17 W CC	62,752	15,527	18,333	0.67841	118.08
025	SEIZURE & HEADACHE AGE >17 W/O CC	27,866	9,702	8,726	0.42393	89.94
026	SEIZURE & HEADACHE AGE 0-17	18	28,187	42,884	1.23158	152.14
027	TRAUMATIC STUPOR & COMA, COMA >1 HR	5,321	21,313	29,196	0.93126	136.99
028	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE >17 W CC	17,277	20,615	24,252	0.90074	117.64
029	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE >17 W/O CC	6,224	11,338	10,844	0.49540	95.64
031	CONCUSSION AGE >17 W CC	5,076	15,157	18,027	0.66225	118.94
032	CONCUSSION AGE >17 W/O CC	1,981	9,856	8,131	0.43065	82.50
034	OTHER DISORDERS OF NERVOUS SYSTEM W CC	27,263	15,688	19,402	0.68546	123.67
035	OTHER DISORDERS OF NERVOUS SYSTEM W/O CC	7,766	9,876	8,350	0.43152	84.55
036	RETINAL PROCEDURES	1,371	11,973	7,803	0.52315	65.17
037	ORBITAL PROCEDURES	1,214	19,084	22,776	0.83383	119.35
038	PRIMARY IRIS PROCEDURES	53	11,432	11,957	0.49949	104.60

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
039	LENS PROCEDURES WITH OR WITHOUT VITRECTOMY	429	11,540	13,915	0.50424	120.58
040	EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE >17	1,352	15,236	12,157	0.66571	79.79
042	INTRAOCULAR PROCEDURES EXCEPT RETINA, IRIS & LENS	1,110	12,667	12,119	0.55349	95.67
043	HYPHEMA	121	9,623	10,753	0.42047	111.74
044	ACUTE MAJOR EYE INFECTIONS	1,147	10,796	12,769	0.47173	118.27
045	NEUROLOGICAL EYE DISORDERS	2,768	11,762	14,280	0.51391	121.41
046	OTHER DISORDERS OF THE EYE AGE >17 W CC	3,735	11,893	12,824	0.51965	107.83
047	OTHER DISORDERS OF THE EYE AGE >17 W/O CC	1,309	8,256	7,270	0.36073	88.05
049	MAJOR HEAD & NECK PROCEDURES	2,438	25,959	25,549	1.13426	98.42
050	SIALOADENECTOMY	2,140	13,619	13,067	0.59507	95.95
051	SALIVARY GLAND PROCEDURES EXCEPT SIALOADENECTOMY	188	13,856	9,926	0.60540	71.64
052	CLEFT LIP & PALATE REPAIR	165	13,224	12,118	0.57782	91.64
053	SINUS & MASTOID PROCEDURES AGE >17	2,206	20,762	23,448	0.90718	112.94
055	MISCELLANEOUS EAR, NOSE, MOUTH & THROAT PROCEDURES	1,330	15,205	18,970	0.66437	124.76
056	RHINOPLASTY	442	13,548	10,567	0.59197	77.99
057	T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	694	17,870	23,482	0.78080	131.41
059	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	101	13,079	17,860	0.57149	136.55
060	TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0-17	8	12,557	10,721	0.54865	85.38
061	MYRINGOTOMY W TUBE INSERTION AGE >17	211	20,277	20,829	0.88600	102.72
063	OTHER EAR, NOSE, MOUTH & THROAT O.R. PROCEDURES	2,815	21,978	25,105	0.96031	114.23
064	EAR, NOSE, MOUTH & THROAT MALIGNANCY	3,300	18,219	23,038	0.79606	126.45
065	DYSEQUILIBRIUM	40,744	9,482	8,258	0.41430	87.09
066	EPISTAXIS	7,899	9,384	11,845	0.41002	126.23
067	EPIGLOTTITIS	413	11,911	12,803	0.52043	107.49
068	OTITIS MEDIA & URI AGE >17 W CC	17,098	10,348	10,849	0.45213	104.84
069	OTITIS MEDIA & URI AGE >17 W/O CC	4,781	7,531	6,142	0.32908	81.56
070	OTITIS MEDIA & URI AGE 0-17	26	6,716	3,153	0.29345	46.94
071	LARYNGOTRACHEITIS	67	11,615	11,840	0.50748	101.94
072	NASAL TRAUMA & DEFORMITY	1,043	11,913	11,841	0.52053	99.39
073	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE >17	7,845	12,885	14,557	0.56301	112.97
074	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE 0-17	4	5,390	2,998	0.23549	55.63
075	MAJOR CHEST PROCEDURES	44,187	47,742	50,621	2.08601	106.03
076	OTHER RESP SYSTEM O.R. PROCEDURES W CC	46,467	44,230	57,692	1.93256	130.44
077	OTHER RESP SYSTEM O.R. PROCEDURES W/O CC	2,132	18,536	15,541	0.80989	83.85
078	PULMONARY EMBOLISM	44,721	19,010	16,003	0.83061	84.18
079	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	167,526	24,403	25,863	1.06628	105.98
080	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W/O CC	7,629	13,511	13,438	0.59035	99.46
081	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE 0-17	5	24,057	15,546	1.05115	64.62

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
082	RESPIRATORY NEOPLASMS	64,051	21,471	22,485	0.93815	104.72
083	MAJOR CHEST TRAUMA W CC	6,948	15,142	14,855	0.66163	98.10
084	MAJOR CHEST TRAUMA W/O CC	1,478	9,060	7,494	0.39588	82.72
085	PLEURAL EFFUSION W CC	21,517	18,977	19,608	0.82919	103.32
086	PLEURAL EFFUSION W/O CC	1,838	10,795	10,093	0.47169	93.49
087	PULMONARY EDEMA & RESPIRATORY FAILURE	80,610	21,168	25,048	0.92492	118.33
088	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	407,780	13,695	14,239	0.59839	103.97
089	SIMPLE PNEUMONIA & PLEURISY AGE >17 W CC	541,822	15,900	15,932	0.69474	100.20
090	SIMPLE PNEUMONIA & PLEURISY AGE >17 W/O CC	45,359	9,434	7,767	0.41221	82.33
091	SIMPLE PNEUMONIA & PLEURISY AGE 0-17	48	12,852	11,942	0.56157	92.92
092	INTERSTITIAL LUNG DISEASE W CC	16,189	18,304	17,396	0.79978	95.04
093	INTERSTITIAL LUNG DISEASE W/O CC	1,580	11,012	8,979	0.48114	81.54
094	PNEUMOTHORAX W CC	13,189	17,640	18,175	0.77074	103.04
095	PNEUMOTHORAX W/O CC	1,600	9,394	8,542	0.41045	90.93
096	BRONCHITIS & ASTHMA AGE >17 W CC	58,285	11,378	10,931	0.49717	96.06
097	BRONCHITIS & ASTHMA AGE >17 W/O CC	26,792	8,305	7,162	0.36286	86.24
098	BRONCHITIS & ASTHMA AGE 0-17	9	6,184	2,292	0.27022	37.07
099	RESPIRATORY SIGNS & SYMPTOMS W CC	21,238	11,067	10,820	0.48355	97.77
100	RESPIRATORY SIGNS & SYMPTOMS W/O CC	6,862	8,443	6,791	0.36889	80.44
101	OTHER RESPIRATORY SYSTEM DIAGNOSES W CC	22,829	13,540	14,278	0.59163	105.45
102	OTHER RESPIRATORY SYSTEM DIAGNOSES W/O CC	5,174	8,513	6,918	0.37196	81.27
103	HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM	742	327,306	305,991	14.30119	93.49
104	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W CARD CATH	20,738	122,580	85,583	5.35595	69.82
105	CARDIAC VALVE & OTH MAJOR CARDIOTHORACIC PROC W/O CARD CATH	31,363	90,813	65,892	3.96795	72.56
106	CORONARY BYPASS W PTCA	3,480	109,963	66,280	4.80471	60.27
107	CORONARY BYPASS W CARDIAC CATH	69,286	82,617	52,523	3.60985	63.57
108	OTHER CARDIOTHORACIC PROCEDURES	8,738	82,395	66,254	3.60014	80.41
109	CORONARY BYPASS W/O PTCA OR CARDIAC CATH	50,184	61,756	46,306	2.69834	74.98
110	MAJOR CARDIOVASCULAR PROCEDURES W CC	56,233	60,842	54,397	2.65841	89.41
111	MAJOR CARDIOVASCULAR PROCEDURES W/O CC	9,940	38,862	23,167	1.69804	59.61
113	AMPUTATION FOR CIRC SYSTEM DISORDERS EXCEPT UPPER LIMB & TOE	36,624	44,130	55,010	1.92820	124.65
114	UPPER LIMB & TOE AMPUTATION FOR CIRC SYSTEM DISORDERS	8,419	25,438	29,679	1.11150	116.67
115	PRM CARD PACEM IMPL W AMI/HR/SHOCK OR AICD LEAD OR GNRTR	21,904	56,171	40,383	2.45431	71.89
116	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT	117,242	35,958	23,674	1.57114	65.84
117	CARDIAC PACEMAKER REVISION EXCEPT DEVICE REPLACEMENT	5,072	20,815	24,270	0.90950	116.59
118	CARDIAC PACEMAKER DEVICE REPLACEMENT	7,546	25,757	18,166	1.12542	70.53
119	VEIN LIGATION & STRIPPING	977	21,282	25,571	0.92987	120.15
120	OTHER CIRCULATORY SYSTEM O.R. PROCEDURES	35,735	36,822	55,104	1.60890	149.65

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
121	CIRCULATORY DISORDERS W AMI & MAJOR COMP, DISCHARGED ALIVE	156,174	23,760	24,159	1.03817	101.68
122	CIRCULATORY DISORDERS W AMI W/O MAJOR COMP, DISCHARGED ALIVE	60,755	14,660	12,285	0.64053	83.80
123	CIRCULATORY DISORDERS W AMI, EXPIRED	33,104	24,194	33,625	1.05711	138.99
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG	128,770	22,329	19,759	0.97563	88.49
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG	95,311	17,020	11,065	0.74365	65.01
126	ACUTE & SUBACUTE ENDOCARDITIS	5,704	40,643	43,752	1.77585	107.65
127	HEART FAILURE & SHOCK	682,707	16,019	18,141	0.69994	113.25
128	DEEP VEIN THROMBOPHLEBITIS	5,092	10,807	11,480	0.47220	106.22
129	CARDIAC ARREST, UNEXPLAINED	3,727	16,223	21,695	0.70886	133.73
130	PERIPHERAL VASCULAR DISORDERS W CC	87,658	14,404	16,373	0.62937	113.67
131	PERIPHERAL VASCULAR DISORDERS W/O CC	23,491	8,575	7,853	0.37468	91.57
132	ATHEROSCLEROSIS W CC	114,687	9,735	9,936	0.42537	102.06
133	ATHEROSCLEROSIS W/O CC	7,208	8,430	7,502	0.36835	88.99
134	HYPERTENSION	41,741	9,488	9,327	0.41457	98.30
135	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W CC	7,330	13,906	15,690	0.60761	112.83
136	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W/O CC	1,119	9,804	9,037	0.42837	92.18
138	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS W CC	203,224	12,979	14,773	0.56711	113.82
139	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS W/O CC	77,661	8,212	7,043	0.35881	85.77
140	ANGINA PECTORIS	37,586	7,916	7,126	0.34586	90.02
141	SYNCOPE & COLLAPSE W CC	119,223	11,957	10,928	0.52242	91.40
142	SYNCOPE & COLLAPSE W/O CC	51,295	9,317	7,329	0.40710	78.67
143	CHEST PAIN	244,574	8,943	7,274	0.39074	81.33
144	OTHER CIRCULATORY SYSTEM DIAGNOSES W CC	97,745	19,763	29,089	0.86354	147.18
145	OTHER CIRCULATORY SYSTEM DIAGNOSES W/O CC	6,089	9,173	9,425	0.40080	102.74
146	RECTAL RESECTION W CC	10,589	40,977	35,545	1.79044	86.74
147	RECTAL RESECTION W/O CC	2,611	22,886	13,629	0.99995	59.55
148	MAJOR SMALL & LARGE BOWEL PROCEDURES W CC	133,247	52,781	56,623	2.30618	107.28
149	MAJOR SMALL & LARGE BOWEL PROCEDURES W/O CC	19,617	22,268	14,323	0.97297	64.32
150	PERITONEAL ADHESIOLYSIS W CC	22,282	43,435	43,335	1.89782	99.77
151	PERITONEAL ADHESIOLYSIS W/O CC	5,263	19,749	13,408	0.86290	67.89
152	MINOR SMALL & LARGE BOWEL PROCEDURES W CC	4,932	29,493	30,536	1.28865	103.54
153	MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC	2,079	16,857	10,734	0.73655	63.68
154	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W CC	28,058	62,189	71,170	2.71725	114.44
155	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W/O CC	6,098	20,052	16,213	0.87616	80.85
156	STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE 0-17	5	133,783	166,984	5.84548	124.82
157	ANAL & STOMAL PROCEDURES W CC	8,155	20,651	23,816	0.90231	115.33
158	ANAL & STOMAL PROCEDURES W/O CC	4,085	10,339	7,884	0.45175	76.25
159	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W CC	18,927	22,007	23,261	0.96156	105.70

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
160	HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W/O CC	11,893	13,129	8,308	0.57363	63.28
161	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W CC	10,245	18,850	21,110	0.82361	111.99
162	INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W/O CC	5,434	10,614	7,530	0.46377	70.94
163	HERNIA PROCEDURES AGE 0-17	10	10,730	7,752	0.46884	72.24
164	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W CC	5,864	35,279	33,225	1.54149	94.18
165	APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W/O CC	2,503	18,573	11,270	0.81151	60.68
166	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W CC	4,896	22,724	22,609	0.99290	99.49
167	APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W/O CC	4,611	13,977	7,723	0.61069	55.26
168	MOUTH PROCEDURES W CC	1,522	19,966	22,163	0.87239	111.00
169	MOUTH PROCEDURES W/O CC	756	11,397	8,536	0.49800	74.90
170	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W CC	17,188	45,303	51,533	1.97946	113.75
171	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC	1,468	18,507	13,602	0.80865	73.49
172	DIGESTIVE MALIGNANCY W CC	32,341	21,877	26,287	0.95591	120.16
173	DIGESTIVE MALIGNANCY W/O CC	2,369	11,651	11,649	0.50909	99.98
174	G.I. HEMORRHAGE W CC	263,142	15,782	16,877	0.68958	106.94
175	G.I. HEMORRHAGE W/O CC	32,136	8,876	7,501	0.38783	84.51
176	COMPLICATED PEPTIC ULCER	14,357	17,557	19,437	0.76713	110.71
177	UNCOMPLICATED PEPTIC ULCER W CC	8,488	14,266	13,621	0.62332	95.48
178	UNCOMPLICATED PEPTIC ULCER W/O CC	2,893	10,912	8,127	0.47679	74.48
179	INFLAMMATORY BOWEL DISEASE	14,241	17,261	21,357	0.75418	123.74
180	G.I. OBSTRUCTION W CC	90,825	15,144	18,288	0.66171	120.76
181	G.I. OBSTRUCTION W/O CC	25,607	8,767	7,547	0.38308	86.09
182	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE >17 W CC	287,677	13,175	15,304	0.57567	116.16
183	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE >17 W/O CC	85,517	9,139	7,315	0.39932	80.04
184	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE 0-17	80	9,163	15,676	0.40035	171.09
185	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE >17	5,608	13,688	17,068	0.59807	124.69
186	DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE 0-17	4	4,181	3,583	0.18270	85.70
187	DENTAL EXTRACTIONS & RESTORATIONS	620	13,208	12,810	0.57711	96.99
188	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE >17 W CC	89,276	17,547	23,922	0.76671	136.33
189	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE >17 W/O CC	13,021	9,491	10,524	0.41468	110.89
190	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE 0-17	64	9,182	8,905	0.40119	96.98
191	PANCREAS, LIVER & SHUNT PROCEDURES W CC	10,196	61,405	75,538	2.68301	123.02
192	PANCREAS, LIVER & SHUNT PROCEDURES W/O CC	1,305	26,346	19,911	1.15117	75.57
193	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W CC	4,421	50,597	49,291	2.21078	97.42
194	BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC	513	24,598	20,333	1.07479	82.66
195	CHOLECYSTECTOMY W C.D.E. W CC	3,217	47,379	43,588	2.07016	92.00
196	CHOLECYSTECTOMY W C.D.E. W/O CC	695	24,870	15,655	1.08668	62.95
197	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W CC	16,973	39,158	39,816	1.71097	101.68

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
198	CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W/O CC	4,570	17,982	12,449	0.78569	69.23
199	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR MALIGNANCY	1,386	37,703	40,530	1.64738	107.50
200	HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR NON-MALIGNANCY	904	41,982	53,508	1.83436	127.45
201	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES	2,619	58,840	70,314	2.57094	119.50
202	CIRRHOSIS & ALCOHOLIC HEPATITIS	26,917	20,841	26,798	0.91060	128.59
203	MALIGNANCY OF HEPATOBILIARY SYSTEM OR PANCREAS	31,133	21,223	22,903	0.92730	107.92
204	DISORDERS OF PANCREAS EXCEPT MALIGNANCY	71,720	17,528	22,481	0.76585	128.26
205	DISORDERS OF LIVER EXCEPT MALIG,CIRR,ALC HEPA W CC	31,073	18,629	26,333	0.81395	141.36
206	DISORDERS OF LIVER EXCEPT MALIG,CIRR,ALC HEPA W/O CC	2,055	11,429	11,235	0.49936	98.30
207	DISORDERS OF THE BILIARY TRACT W CC	35,193	18,122	19,765	0.79182	109.06
208	DISORDERS OF THE BILIARY TRACT W/O CC	9,647	10,716	8,827	0.46823	82.37
209	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF LOWER EXTREMITY	454,465	30,795	18,291	1.34555	59.40
210	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W CC	126,630	28,194	23,352	1.23189	82.83
211	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W/O CC	26,413	19,340	10,941	0.84503	56.57
212	HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE 0-17	10	20,198	9,740	0.88251	48.23
213	AMPUTATION FOR MUSCULOSKELETAL SYSTEM & CONN TISSUE DISORDERS	10,098	29,503	34,495	1.28909	116.92
216	BIOPSIES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE	17,587	29,291	27,322	1.27985	93.27
217	WND DEBRID & SKN GRFT EXCEPT HAND,FOR MUSCSKELET & CONN TISS DIS	17,300	44,696	58,397	1.95294	130.65
218	LOWER EXTREM & HUMER PROC EXCEPT HIP,FOOT,FEMUR AGE >17 W CC	28,371	25,321	23,048	1.10637	91.02
219	LOWER EXTREM & HUMER PROC EXCEPT HIP,FOOT,FEMUR AGE >17 W/O CC	21,172	16,223	10,505	0.70885	64.75
220	LOWER EXTREM & HUMER PROC EXCEPT HIP,FOOT,FEMUR AGE 0-17	3	31,135	34,532	1.36041	110.91
223	MAJOR SHOULDER/ELBOW PROC, OR OTHER UPPER EXTREMITY PROC W CC	13,283	17,477	15,234	0.76363	87.17
224	SHOULDER,ELBOW OR FOREARM PROC,EXC MAJOR JOINT PROC, W/O CC	10,819	12,742	7,690	0.55675	60.35
225	FOOT PROCEDURES	6,474	18,865	20,137	0.82430	106.74
226	SOFT TISSUE PROCEDURES W CC	6,557	24,237	30,889	1.05902	127.44
227	SOFT TISSUE PROCEDURES W/O CC	5,035	13,128	9,343	0.57360	71.17
228	MAJOR THUMB OR JOINT PROC,OR OTH HAND OR WRIST PROC W CC	2,605	17,991	16,466	0.78608	91.52
229	HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC	1,189	11,027	8,147	0.48183	73.88
230	LOCAL EXCISION & REMOVAL OF INT FIX DEVICES OF HIP & FEMUR	2,540	20,675	21,284	0.90339	102.94
232	ARTHROSCOPY	708	15,341	12,373	0.67031	80.65
233	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W CC	14,861	29,441	30,135	1.28641	102.36
234	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC	7,604	19,078	12,242	0.83358	64.17
235	FRACTURES OF FEMUR	4,926	11,545	13,792	0.50443	119.46
236	FRACTURES OF HIP & PELVIS	41,863	11,190	13,681	0.48895	122.26
237	SPRAINS, STRAINS, & DISLOCATIONS OF HIP, PELVIS & THIGH	2,000	9,745	10,844	0.42580	111.27
238	OSTEOMYELITIS	9,704	21,413	26,930	0.93561	125.76
239	PATHOLOGICAL FRACTURES & MUSCULOSKELETAL & CONN TISS MALIGNANCY	42,326	16,306	19,294	0.71249	118.32
240	CONNECTIVE TISSUE DISORDERS W CC	12,473	21,830	33,339	0.95381	152.73

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
241	CONNECTIVE TISSUE DISORDERS W/O CC	2,662	10,547	12,402	0.46082	117.60
242	SEPTIC ARTHRITIS	2,691	17,737	23,496	0.77499	132.47
243	MEDICAL BACK PROBLEMS	100,521	12,006	12,664	0.52461	105.48
244	BONE DISEASES & SPECIFIC ARTHROPATHIES W CC	15,448	11,297	14,285	0.49359	126.45
245	BONE DISEASES & SPECIFIC ARTHROPATHIES W/O CC	5,733	7,210	7,435	0.31502	103.12
246	NON-SPECIFIC ARTHROPATHIES	1,403	9,346	9,174	0.40835	98.17
247	SIGNS & SYMPTOMS OF MUSCULOSKELETAL SYSTEM & CONN TISSUE	21,379	9,130	9,304	0.39892	101.91
248	TENDONITIS, MYOSITIS & BURSITIS	14,808	13,589	15,833	0.59375	116.51
249	AFTERCARE, MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE	13,646	11,176	15,098	0.48831	135.10
250	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W CC	4,091	10,894	11,264	0.47599	103.40
251	FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W/O CC	2,134	7,443	5,811	0.32522	78.07
253	FX, SPRN, STRN & DISL OF UPARM,LOWLEG EX FOOT AGE >17 W CC	24,544	11,932	13,896	0.52136	116.46
254	FX, SPRN, STRN & DISL OF UPARM,LOWLEG EX FOOT AGE >17 W/O CC	10,319	7,158	6,138	0.31277	85.75
256	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES	7,058	13,024	16,958	0.56905	130.21
257	TOTAL MASTECTOMY FOR MALIGNANCY W CC	13,296	14,023	11,640	0.61273	83.00
258	TOTAL MASTECTOMY FOR MALIGNANCY W/O CC	11,895	11,122	6,741	0.48597	60.61
259	SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC	2,849	15,263	14,057	0.66688	92.10
260	SUBTOTAL MASTECTOMY FOR MALIGNANCY W/O CC	2,956	10,953	6,518	0.47859	59.51
261	BREAST PROC FOR NON-MALIGNANCY EXCEPT BIOPSY & LOCAL EXCISION	1,598	15,416	15,119	0.67360	98.07
262	BREAST BIOPSY & LOCAL EXCISION FOR NON-MALIGNANCY	629	15,250	13,829	0.66632	90.68
263	SKIN GRAFT &/OR DEBRID FOR SKN ULCER OR CELLULITIS W CC	23,375	30,716	42,096	1.34210	137.05
264	SKIN GRAFT &/OR DEBRID FOR SKN ULCER OR CELLULITIS W/O CC	3,883	15,810	14,158	0.69081	89.55
265	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W CC	4,228	25,491	35,302	1.11378	138.49
266	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W/O CC	2,276	13,595	10,504	0.59400	77.26
267	PERIANAL & PILONIDAL PROCEDURES	267	13,982	14,020	0.61091	100.28
268	SKIN, SUBCUTANEOUS TISSUE & BREAST PLASTIC PROCEDURES	1,011	17,829	16,038	0.77901	89.96
269	OTHER SKIN, SUBCUT TISS & BREAST PROC W CC	10,513	27,710	35,225	1.21077	127.12
270	OTHER SKIN, SUBCUT TISS & BREAST PROC W/O CC	2,621	12,843	10,674	0.56116	83.11
271	SKIN ULCERS	20,653	15,142	19,654	0.66163	129.79
272	MAJOR SKIN DISORDERS W CC	5,839	15,225	20,465	0.66522	134.42
273	MAJOR SKIN DISORDERS W/O CC	1,339	8,633	7,556	0.37721	87.52
274	MALIGNANT BREAST DISORDERS W CC	2,260	17,680	19,705	0.77250	111.45
275	MALIGNANT BREAST DISORDERS W/O CC	226	8,337	7,724	0.36429	92.64
276	NON-MALIGANT BREAST DISORDERS	1,429	10,777	11,355	0.47088	105.36
277	CELLULITIS AGE >17 W CC	110,543	13,436	15,363	0.58708	114.34
278	CELLULITIS AGE >17 W/O CC	33,443	8,394	7,718	0.36675	91.96
279	CELLULITIS AGE 0-17	8	12,286	7,002	0.53683	56.99
280	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE >17 W CC	19,082	11,315	11,782	0.49440	104.13

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
281	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE >17 W/O CC	7,026	7,723	6,408	0.33746	82.97
283	MINOR SKIN DISORDERS W CC	6,166	11,605	15,286	0.50705	131.73
284	MINOR SKIN DISORDERS W/O CC	1,814	7,241	7,734	0.31640	106.80
285	AMPUTAT OF LOWER LIMB FOR ENDOCRINE,NUTRIT,& METABOL DISORDERS	7,514	32,298	45,097	1.41122	139.63
286	ADRENAL & PITUITARY PROCEDURES	2,645	30,548	36,089	1.33475	118.14
287	SKIN GRAFTS & WOUND DEBRID FOR ENDOC, NUTRIT & METAB DISORDERS	6,039	28,754	37,966	1.25638	132.04
288	O.R. PROCEDURES FOR OBESITY	10,467	31,660	33,335	1.38334	105.29
289	PARATHYROID PROCEDURES	6,772	14,666	16,217	0.64081	110.58
290	THYROID PROCEDURES	10,687	14,003	14,846	0.61183	106.02
291	THYROGLOSSAL PROCEDURES	63	18,519	37,968	0.80917	205.02
292	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W CC	7,148	40,739	43,253	1.78002	106.17
293	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC	365	20,983	18,934	0.91681	90.24
294	DIABETES AGE >35	97,493	11,889	15,418	0.51948	129.68
295	DIABETES AGE 0-35	4,072	11,331	12,980	0.49510	114.55
296	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W CC	249,976	12,680	15,244	0.55402	120.22
297	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W/O CC	44,710	7,629	6,942	0.33334	91.00
298	NUTRITIONAL & MISC METABOLIC DISORDERS AGE 0-17	85	8,580	11,926	0.37491	138.99
299	INBORN ERRORS OF METABOLISM	1,471	15,957	20,485	0.69721	128.38
300	ENDOCRINE DISORDERS W CC	20,907	16,961	19,253	0.74108	113.52
301	ENDOCRINE DISORDERS W/O CC	3,839	9,620	9,064	0.42035	94.21
302	KIDNEY TRANSPLANT	9,673	83,819	49,410	3.66237	58.95
303	KIDNEY,URETER & MAJOR BLADDER PROCEDURES FOR NEOPLASM	23,368	34,923	33,770	1.52593	96.70
304	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W CC	13,606	36,684	42,963	1.60287	117.12
305	KIDNEY,URETER & MAJOR BLADDER PROC FOR NON-NEOPL W/O CC	3,061	17,999	11,885	0.78645	66.03
306	PROSTATECTOMY W CC	6,212	20,096	22,199	0.87808	110.46
307	PROSTATECTOMY W/O CC	2,031	9,695	6,101	0.42361	62.93
308	MINOR BLADDER PROCEDURES W CC	6,955	25,736	35,916	1.12451	139.55
309	MINOR BLADDER PROCEDURES W/O CC	3,529	14,170	9,514	0.61913	67.15
310	TRANSURETHRAL PROCEDURES W CC	25,593	18,730	22,288	0.81839	119.00
311	TRANSURETHRAL PROCEDURES W/O CC	6,416	10,022	6,494	0.43788	64.80
312	URETHRAL PROCEDURES, AGE >17 W CC	1,435	17,607	19,397	0.76930	110.17
313	URETHRAL PROCEDURES, AGE >17 W/O CC	506	10,615	6,664	0.46381	62.78
315	OTHER KIDNEY & URINARY TRACT O.R. PROCEDURES	36,054	32,941	40,898	1.43932	124.15
316	RENAL FAILURE	177,037	19,623	24,127	0.85739	122.95
317	ADMIT FOR RENAL DIALYSIS	2,718	12,485	14,143	0.54552	113.28
318	KIDNEY & URINARY TRACT NEOPLASMS W CC	5,833	18,078	21,961	0.78992	121.48
319	KIDNEY & URINARY TRACT NEOPLASMS W/O CC	376	10,059	15,240	0.43950	151.51
320	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W CC	214,705	13,350	14,616	0.58330	109.49

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
321	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W/O CC	31,045	8,764	7,322	0.38292	83.55
322	KIDNEY & URINARY TRACT INFECTIONS AGE 0-17	62	8,733	8,213	0.38158	94.04
323	URINARY STONES W CC, &/OR ESW LITHOTRIPSY	20,220	12,805	12,092	0.55950	94.43
324	URINARY STONES W/O CC	5,374	7,803	6,255	0.34094	80.16
325	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W CC	9,477	10,121	11,062	0.44221	109.30
326	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W/O CC	2,547	6,930	6,333	0.30281	91.39
327	KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE 0-17	5	4,106	3,414	0.17941	83.14
328	URETHRAL STRICTURE AGE >17 W CC	598	11,146	10,178	0.48699	91.32
329	URETHRAL STRICTURE AGE >17 W/O CC	71	7,508	5,191	0.32806	69.13
331	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE >17 W CC	53,790	16,448	20,310	0.71866	123.48
332	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE >17 W/O CC	4,332	9,590	10,044	0.41903	104.74
333	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE 0-17	253	16,446	29,036	0.71860	176.55
334	MAJOR MALE PELVIC PROCEDURES W CC	9,718	22,478	20,316	0.98215	90.38
335	MAJOR MALE PELVIC PROCEDURES W/O CC	11,890	17,162	9,512	0.74988	55.43
336	TRANSURETHRAL PROSTATECTOMY W CC	30,662	13,230	14,804	0.57806	111.90
337	TRANSURETHRAL PROSTATECTOMY W/O CC	24,791	8,989	5,177	0.39278	57.59
338	TESTES PROCEDURES, FOR MALIGNANCY	641	21,364	23,231	0.93349	108.74
339	TESTES PROCEDURES, NON-MALIGNANCY AGE >17	1,238	18,541	21,903	0.81013	118.13
340	TESTES PROCEDURES, NON-MALIGNANCY AGE 0-17	2	13,498	6,263	0.58977	46.40
341	PENIS PROCEDURES	3,137	19,771	23,649	0.86387	119.62
342	CIRCUMCISION AGE >17	559	13,499	14,238	0.58982	105.48
344	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY	2,625	19,664	15,943	0.85919	81.08
345	OTHER MALE REPRODUCTIVE SYSTEM O.R. PROC EXCEPT FOR MALIGNANCY	1,427	17,993	24,497	0.78617	136.15
346	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W CC	3,902	16,347	19,736	0.71428	120.73
347	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W/O CC	247	9,719	11,875	0.42464	122.18
348	BENIGN PROSTATIC HYPERTROPHY W CC	4,129	11,335	12,196	0.49529	107.59
349	BENIGN PROSTATIC HYPERTROPHY W/O CC	572	6,637	6,501	0.28998	97.96
350	INFLAMMATION OF THE MALE REPRODUCTIVE SYSTEM	7,049	11,363	12,223	0.49647	107.57
352	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES	959	11,420	12,311	0.49899	107.80
353	PELVIC EVISCERATION, RADICAL HYSTERECTOMY & RADICAL VULVECTOMY	2,691	31,250	55,268	1.36541	176.86
354	UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W CC	7,462	24,066	25,435	1.05153	105.69
355	UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W/O CC	4,861	13,894	8,234	0.60709	59.26
356	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES	23,675	11,524	7,571	0.50355	65.70
357	UTERINE & ADNEXA PROC FOR OVARIAN OR ADNEXAL MALIGNANCY	5,483	35,094	38,363	1.53338	109.31
358	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W CC	20,472	17,898	17,589	0.78203	98.28
359	UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W/O CC	28,544	12,343	7,099	0.53930	57.52
360	VAGINA, CERVIX & VULVA PROCEDURES	14,606	13,387	11,506	0.58492	85.95
361	LAPAROSCOPY & INCISIONAL TUBAL INTERRUPTION	271	17,180	13,584	0.75066	79.07

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
362	ENDOSCOPIC TUBAL INTERRUPTION	2	8,349	3,793	0.36481	45.44
363	D&C, CONIZATION & RADIO-IMPLANT, FOR MALIGNANCY	2,105	15,258	15,972	0.66670	104.68
364	D&C, CONIZATION EXCEPT FOR MALIGNANCY	1,437	13,701	14,354	0.59865	104.77
365	OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES	1,594	32,150	42,595	1.40476	132.49
366	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W CC	4,713	19,239	22,453	0.84061	116.71
367	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W/O CC	443	9,083	8,948	0.39687	98.52
368	INFECTIONS, FEMALE REPRODUCTIVE SYSTEM	3,840	18,531	23,576	0.80969	127.23
369	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS	3,572	9,977	13,274	0.43593	133.04
370	CESAREAN SECTION W CC	1,856	14,250	16,502	0.62263	115.81
371	CESAREAN SECTION W/O CC	2,285	9,461	6,111	0.41340	64.59
372	VAGINAL DELIVERY W COMPLICATING DIAGNOSES	1,156	7,870	9,416	0.34388	119.64
373	VAGINAL DELIVERY W/O COMPLICATING DIAGNOSES	4,919	5,591	3,855	0.24427	68.96
374	VAGINAL DELIVERY W STERILIZATION &/OR D&C	159	10,548	9,993	0.46087	94.74
375	VAGINAL DELIVERY W O.R. PROC EXCEPT STERIL &/OR D&C	6	56,432	90,239	2.46573	159.91
376	POSTPARTUM & POST ABORTION DIAGNOSES W/O O.R. PROCEDURE	393	8,362	11,108	0.36537	132.84
377	POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE	77	26,453	43,867	1.15581	165.83
378	ECTOPIC PREGNANCY	194	11,612	8,278	0.50738	71.29
379	THREATENED ABORTION	506	5,636	6,540	0.24627	116.04
380	ABORTION W/O D&C	91	6,161	6,055	0.26918	98.29
381	ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY	215	9,450	7,742	0.41290	81.93
382	FALSE LABOR	41	3,278	3,332	0.14322	101.66
383	OTHER ANTEPARTUM DIAGNOSES W MEDICAL COMPLICATIONS	2,470	8,004	12,673	0.34974	158.32
384	OTHER ANTEPARTUM DIAGNOSES W/O MEDICAL COMPLICATIONS	131	5,066	5,708	0.22133	112.69
392	SPLENECTOMY AGE >17	2,178	47,502	54,100	2.07556	113.89
394	OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS	2,785	30,006	41,992	1.31109	139.94
395	RED BLOOD CELL DISORDERS AGE >17	113,994	12,934	16,295	0.56513	125.99
396	RED BLOOD CELL DISORDERS AGE 0-17	10	12,252	18,554	0.53534	151.43
397	COAGULATION DISORDERS	18,033	22,090	55,248	0.96520	250.10
398	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W CC	17,962	19,058	25,786	0.83272	135.30
399	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W/O CC	1,624	10,452	9,803	0.45667	93.79
401	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W CC	6,247	45,827	56,435	2.00233	123.15
402	LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W/O CC	1,395	18,364	17,037	0.80240	92.77
403	LYMPHOMA & NON-ACUTE LEUKEMIA W CC	31,315	28,331	37,159	1.23790	131.16
404	LYMPHOMA & NON-ACUTE LEUKEMIA W/O CC	3,767	14,419	15,561	0.63004	107.91
406	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W CC	2,184	44,237	52,619	1.93290	118.95
407	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R.PROC W/O CC	580	19,266	15,508	0.84179	80.49
408	MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R.PROC	2,146	35,521	53,158	1.55204	149.65
409	RADIOTHERAPY	1,781	19,158	20,151	0.83709	105.18

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
410	CHEMOTHERAPY W/O ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS	27,756	17,583	18,814	0.76826	107.00
411	HISTORY OF MALIGNANCY W/O ENDOSCOPY	12	5,786	4,318	0.25279	74.63
412	HISTORY OF MALIGNANCY W ENDOSCOPY	12	13,289	16,251	0.58066	122.29
413	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W CC	5,126	20,350	22,515	0.88917	110.64
414	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W/O CC	569	12,425	13,888	0.54287	111.78
415	O.R. PROCEDURE FOR INFECTIOUS & PARASITIC DISEASES	49,629	58,843	73,808	2.57108	125.43
416	SEPTICEMIA AGE >17	233,559	25,943	33,960	1.13353	130.90
417	SEPTICEMIA AGE 0-17	20	16,197	32,688	0.70770	201.82
418	POSTOPERATIVE & POST-TRAUMATIC INFECTIONS	28,060	16,818	22,453	0.73484	133.50
419	FEVER OF UNKNOWN ORIGIN AGE >17 W CC	16,070	13,304	13,995	0.58131	105.19
420	FEVER OF UNKNOWN ORIGIN AGE >17 W/O CC	2,909	9,494	8,981	0.41482	94.60
421	VIRAL ILLNESS AGE >17	11,672	12,031	16,830	0.52568	139.89
422	VIRAL ILLNESS & FEVER OF UNKNOWN ORIGIN AGE 0-17	52	9,601	15,947	0.41950	166.09
423	OTHER INFECTIOUS & PARASITIC DISEASES DIAGNOSES	8,472	29,795	44,674	1.30184	149.94
424	O.R. PROCEDURE W PRINCIPAL DIAGNOSES OF MENTAL ILLNESS	1,038	36,363	87,952	1.58882	241.87
425	ACUTE ADJUSTMENT REACTION & PSYCHOSOCIAL DYSFUNCTION	14,558	9,669	9,902	0.42249	102.41
426	DEPRESSIVE NEUROSES	4,087	7,334	6,999	0.32046	95.43
427	NEUROSES EXCEPT DEPRESSIVE	1,441	7,850	8,374	0.34298	106.68
428	DISORDERS OF PERSONALITY & IMPULSE CONTROL	707	11,460	18,265	0.50074	159.38
429	ORGANIC DISTURBANCES & MENTAL RETARDATION	24,927	12,036	13,816	0.52592	114.79
430	PSYCHOSES	66,018	10,105	10,724	0.44150	106.13
431	CHILDHOOD MENTAL DISORDERS	294	8,051	10,405	0.35179	129.23
432	OTHER MENTAL DISORDER DIAGNOSES	401	9,952	9,777	0.43482	98.24
433	ALCOHOL/DRUG ABUSE OR DEPENDENCE, LEFT AMA	5,140	4,480	5,045	0.19574	112.62
439	SKIN GRAFTS FOR INJURIES	1,727	30,742	46,770	1.34322	152.14
440	WOUND DEBRIDEMENTS FOR INJURIES	5,504	29,006	51,416	1.26738	177.26
441	HAND PROCEDURES FOR INJURIES	771	14,693	16,738	0.64200	113.92
442	OTHER O.R. PROCEDURES FOR INJURIES W CC	17,766	39,160	54,488	1.71106	139.14
443	OTHER O.R. PROCEDURES FOR INJURIES W/O CC	3,355	15,441	12,954	0.67469	83.89
444	TRAUMATIC INJURY AGE >17 W CC	5,821	11,707	15,515	0.51151	132.53
445	TRAUMATIC INJURY AGE >17 W/O CC	2,341	7,887	7,102	0.34461	90.04
447	ALLERGIC REACTIONS AGE >17	6,070	8,875	12,917	0.38778	145.54
449	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W CC	38,407	13,403	18,656	0.58562	139.19
450	POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC	7,789	6,738	6,284	0.29441	93.27
451	POISONING & TOXIC EFFECTS OF DRUGS AGE 0-17	3	4,179	2,937	0.18257	70.28
452	COMPLICATIONS OF TREATMENT W CC	27,086	16,494	25,105	0.72070	152.20
453	COMPLICATIONS OF TREATMENT W/O CC	5,377	8,321	9,741	0.36359	117.06
454	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W CC	3,751	12,958	17,902	0.56618	138.15

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
455	OTHER INJURY, POISONING & TOXIC EFFECT DIAG W/O CC	837	7,474	6,328	0.32657	84.67
461	O.R. PROC W DIAGNOSES OF OTHER CONTACT W HEALTH SERVICES	2,621	22,084	28,657	0.96495	129.76
462	REHABILITATION	2,573	15,569	14,461	0.68027	92.89
463	SIGNS & SYMPTOMS W CC	30,473	10,775	11,945	0.47080	110.86
464	SIGNS & SYMPTOMS W/O CC	7,524	7,881	7,277	0.34433	92.34
465	AFTERCARE W HISTORY OF MALIGNANCY AS SECONDARY DIAGNOSIS	217	9,946	11,549	0.43457	116.12
466	AFTERCARE W/O HISTORY OF MALIGNANCY AS SECONDARY DIAGNOSIS	1,337	11,641	25,944	0.50863	222.87
467	OTHER FACTORS INFLUENCING HEALTH STATUS	988	7,652	9,050	0.33433	118.27
468	EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	49,606	60,493	67,648	2.64318	111.83
471	BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY	15,475	47,043	30,116	2.05546	64.02
473	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE >17	8,674	52,345	75,433	2.28715	144.11
475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	114,163	55,295	61,826	2.41605	111.81
476	PROSTATIC O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	2,961	36,130	78,357	1.57864	216.88
477	NON-EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	29,008	31,755	40,515	1.38747	127.59
478	OTHER VASCULAR PROCEDURES W CC	111,252	37,550	38,915	1.64070	103.63
479	OTHER VASCULAR PROCEDURES W/O CC	24,278	22,570	16,855	0.98615	74.68
480	LIVER TRANSPLANT AND/OR INTESTINAL TRANSPLANT	1,101	172,930	135,685	7.55595	78.46
481	BONE MARROW TRANSPLANT	1,136	100,138	90,950	4.37541	90.82
482	TRACHEOSTOMY FOR FACE,MOUTH & NECK DIAGNOSES	5,018	48,709	51,309	2.12827	105.34
484	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA	454	81,052	68,169	3.54148	84.11
485	LIMB REATTACHMENT, HIP AND FEMUR PROC FOR MULTIPLE SIGNIFICANT TRA	3,413	49,806	53,467	2.17620	107.35
486	OTHER O.R. PROCEDURES FOR MULTIPLE SIGNIFICANT TRAUMA	2,597	73,217	72,102	3.19911	98.48
487	OTHER MULTIPLE SIGNIFICANT TRAUMA	4,700	29,360	32,957	1.28287	112.25
488	HIV W EXTENSIVE O.R. PROCEDURE	770	72,270	80,109	3.15776	110.85
489	HIV W MAJOR RELATED CONDITION	13,001	29,529	40,547	1.29024	137.31
490	HIV W OR W/O OTHER RELATED CONDITION	5,082	17,188	23,253	0.75101	135.29
491	MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF UPPER EXTREMITY	19,578	26,116	15,136	1.14109	57.96
492	CHEMOTHERAPY W ACUTE LEUKEMIA OR W USE OF HI DOSE CHEMOAGENT	3,971	56,545	65,731	2.47067	116.24
493	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W CC	60,829	28,553	27,938	1.24760	97.84
494	LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC	25,426	15,930	10,221	0.69603	64.16
495	LUNG TRANSPLANT	357	173,840	171,584	7.59573	98.70
496	COMBINED ANTERIOR/POSTERIOR SPINAL FUSION	3,244	99,383	72,322	4.34243	72.77
497	SPINAL FUSION EXCEPT CERVICAL W CC	29,016	57,248	39,988	2.50139	69.85
498	SPINAL FUSION EXCEPT CERVICAL W/O CC	19,410	43,279	25,501	1.89102	58.92
499	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC	35,093	21,860	20,219	0.95515	92.49
500	BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC	48,023	14,231	9,519	0.62179	66.89
501	KNEE PROCEDURES W PDX OF INFECTION W CC	3,071	38,404	36,724	1.67799	95.63
502	KNEE PROCEDURES W PDX OF INFECTION W/O CC	704	21,772	18,686	0.95128	85.83

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
503	KNEE PROCEDURES W/O PDX OF INFECTION	5,856	18,800	17,328	0.82144	92.17
504	EXTEN. BURNS OR FULL THICKNESS BURN W/MV 96+HRS W/SKIN GFT	185	185,734	224,786	8.11539	121.03
505	EXTEN. BURNS OR FULL THICKNESS BURN W/MV 96+HRS W/O SKIN GFT	178	36,658	77,861	1.60171	212.40
506	FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA	990	64,405	80,055	2.81411	124.30
507	FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA	309	27,107	26,950	1.18441	99.42
508	FULL THICKNESS BURN W/O SKIN GRFT OR INHAL INJ W CC OR SIG TRAUMA	632	19,659	25,166	0.85900	128.01
509	FULL THICKNESS BURN W/O SKIN GRFT OR INH INJ W/O CC OR SIG TRAUMA	167	12,701	24,147	0.55496	190.12
510	NON-EXTENSIVE BURNS W CC OR SIGNIFICANT TRAUMA	1,734	18,301	29,157	0.79963	159.32
511	NON-EXTENSIVE BURNS W/O CC OR SIGNIFICANT TRAUMA	622	11,360	34,730	0.49636	305.72
512	SIMULTANEOUS PANCREAS/KIDNEY TRANSPLANT	525	144,919	75,634	6.33205	52.19
513	PANCREAS TRANSPLANT	228	94,111	44,275	4.11205	47.05
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	26,962	84,324	45,507	3.68441	53.97
516	PERCUTANEOUS CARDIOVASC PROC W AMI	38,150	40,323	26,915	1.76184	66.75
517	PERC CARDIO PROC W NON-DRUG ELUTING STENT W/O AMI	65,612	32,029	20,589	1.39945	64.28
518	PERC CARDIO PROC W/O CORONARY ARTERY STENT OR AMI	40,599	27,983	21,512	1.22269	76.87
519	CERVICAL SPINAL FUSION W CC	11,303	38,756	31,834	1.69341	82.14
520	CERVICAL SPINAL FUSION W/O CC	15,258	26,001	14,824	1.13610	57.01
521	ALCOHOL/DRUG ABUSE OR DEPENDENCE W CC	31,575	10,778	13,342	0.47093	123.79
522	ALC/DRUG ABUSE OR DEPEND W REHABILITATION THERAPY W/O CC	5,617	7,340	6,204	0.32070	84.52
523	ALC/DRUG ABUSE OR DEPEND W/O REHABILITATION THERAPY W/O CC	15,611	6,120	6,079	0.26742	99.32
524	TRANSIENT ISCHEMIA	116,665	11,464	9,904	0.50088	86.39
525	OTHER HEART ASSIST SYSTEM IMPLANT	314	179,564	147,282	7.84582	82.02
526	PERCUTNEOUS CARDIOVASULAR PROC W DRUG ELUTING STENT W AMI	54,947	46,298	28,392	2.02292	61.32
527	PERCUTNEOUS CARDIOVASULAR PROC W DRUG ELUTING STENT W/O AMI	189,861	36,412	21,269	1.59096	58.41
528	INTRACRANIAL VASCULAR PROC W PDX HEMORRHAGE	1,740	111,086	77,993	4.85376	70.21
529	VENTRICULAR SHUNT PROCEDURES W CC	3,939	35,195	39,504	1.53780	112.24
530	VENTRICULAR SHUNT PROCEDURES W/O CC	2,317	18,861	11,594	0.82412	61.47
531	SPINAL PROCEDURES W CC	4,720	48,213	54,915	2.10661	113.90
532	SPINAL PROCEDURES W/O CC	2,593	22,408	17,821	0.97909	79.53
533	EXTRACRANIAL PROCEDURES W CC	46,752	24,688	25,416	1.07871	102.95
534	EXTRACRANIAL PROCEDURES W/O CC	44,713	15,912	10,195	0.69524	64.07
535	CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK	12,892	114,209	60,260	4.99023	52.76
536	CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK	19,345	95,302	50,179	4.16411	52.65
537	LOCAL EXCIS & REMOV OF INT FIX DEV EXCEPT HIP & FEMUR W CC	8,505	28,025	28,914	1.22453	103.17
538	LOCAL EXCIS & REMOV OF INT FIX DEV EXCEPT HIP & FEMUR W/O CC	5,539	15,338	10,871	0.67019	70.88
539	LYMPHOMA & LEUKEMIA W MAJOR OR PROCEDURE W CC	4,935	52,112	77,888	2.27698	149.46
540	LYMPHOMA & LEUKEMIA W MAJOR OR PROCEDURE W/O CC	1,485	18,821	17,615	0.82234	93.60
541	TRACH W MV 96+HRS OR PDX EXC FACE,MOUTH, & NECK DX W/MAJ OR	22,173	283,729	242,345	12.39715	85.41

SUMMARY STATISTICS FOR CMS DRGS (v22.0)

CMS DRG	CMS DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
542	TRACH W MV 96+HRS OR PDX EXC FACE, MOUTH, & NECK DX W/O MJ OR	24,078	182,502	175,563	7.97420	96.20
543	CRANIOTOMY W/IMPLANT OF CHEMO AGENT OR ACUTE COMPLEX CNS PDX	5,350	68,063	61,022	2.97391	89.66

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
	Average Coefficient of Variation (Discharge Weighted) Across Consolidated Severity-adjusted DRGs					86.35
	ALL DISCHARGES COMBINED	11,935,210	22,887	35,524	1.00000	155.22
001	LIVER TRANSPLANT AND/OR INTESTINAL TRANSPLANT SOI 1 & 2	331	114,549	47,365	5.00507	41.35
002	LIVER TRANSPLANT AND/OR INTESTINAL TRANSPLANT SOI 3	453	165,452	147,167	7.22923	88.95
003	LIVER TRANSPLANT AND/OR INTESTINAL TRANSPLANT SOI 4	382	324,332	299,191	14.17128	92.25
004	HEART &/OR LUNG TRANSPLANT SOI 1 & 2	325	148,070	124,183	6.46973	83.87
005	HEART &/OR LUNG TRANSPLANT SOI 3	307	233,177	168,473	10.18838	72.25
006	HEART &/OR LUNG TRANSPLANT SOI 4	319	393,123	366,248	17.17699	93.16
007	BONE MARROW TRANSPLANT SOI 1	786	77,936	56,514	3.40529	72.51
008	BONE MARROW TRANSPLANT SOI 2	237	111,879	69,679	4.88840	62.28
009	BONE MARROW TRANSPLANT SOI 3	69	225,092	186,127	9.83511	82.69
010	BONE MARROW TRANSPLANT SOI 4	53	289,448	253,076	12.64705	87.43
011	TRACH W LT MECH VENT W EXTENSIVE PROCEDURE SOI 1 & 2	745	141,763	166,293	6.19416	117.30
012	TRACH W LT MECH VENT W EXTENSIVE PROCEDURE SOI 3	4,565	245,175	221,161	10.71261	90.21
013	TRACH W LT MECH VENT W EXTENSIVE PROCEDURE SOI 4	13,586	308,219	244,606	13.46721	79.36
014	TRACH W LT MECH VENT W/O EXTENSIVE PROCEDURE SOI 1 & 2	1,242	105,538	139,981	4.61136	132.64
015	TRACH W LT MECH VENT W/O EXTENSIVE PROCEDURE SOI 3	7,736	160,664	156,633	7.01999	97.49
016	TRACH W LT MECH VENT W/O EXTENSIVE PROCEDURE SOI 4	14,129	217,447	191,073	9.50108	87.87
017	PANCREAS TRANSPLANT SOI 1 & 2	400	113,140	56,782	4.94348	50.19
018	PANCREAS TRANSPLANT SOI 3	308	129,599	60,983	5.66266	47.05
019	PANCREAS TRANSPLANT SOI 4	89	274,773	232,918	12.00583	84.77
020	NERVOUS SYSTEM PROCDURES SOI 4	6,885	106,351	87,606	4.64687	82.37
021	CRANIOTOMY FOR TRAUMA SOI 1	4,046	32,398	24,696	1.41558	76.23
022	CRANIOTOMY FOR TRAUMA SOI 2	573	42,980	33,909	1.87795	78.90
023	CRANIOTOMY FOR TRAUMA SOI 3	2,174	59,959	66,130	2.61984	110.29
024	CRANIOTOMY EXCEPT FOR TRAUMA SOI 1	10,821	31,983	22,294	1.39746	69.71
025	CRANIOTOMY EXCEPT FOR TRAUMA SOI 2	10,646	45,315	32,718	1.98000	72.20
026	CRANIOTOMY EXCEPT FOR TRAUMA SOI 3	5,125	70,388	54,763	3.07552	77.80
027	VENTRICULAR SHUNT PROCEDURES SOI 1	1,689	18,513	12,367	0.80890	66.80
028	VENTRICULAR SHUNT PROCEDURES SOI 2	3,493	24,477	18,863	1.06948	77.06
029	VENTRICULAR SHUNT PROCEDURES SOI 3	877	52,499	48,715	2.29387	92.79
030	SPINAL PROCEDURES SOI 1	2,936	22,343	17,938	0.97624	80.28
031	SPINAL PROCEDURES SOI 2	2,410	31,500	23,963	1.37637	76.07
032	SPINAL PROCEDURES SOI 3	1,554	65,489	52,173	2.86144	79.67
033	EXTRACRANIAL VASCULAR PROCEDURES SOI 1	50,703	16,115	10,635	0.70414	65.99
034	EXTRACRANIAL VASCULAR PROCEDURES SOI 2	34,949	21,321	16,657	0.93159	78.13
035	EXTRACRANIAL VASCULAR PROCEDURES SOI 3	7,016	44,295	39,366	1.93542	88.87

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
036	OTHER NERVOUS SYSTEM & RELATED PROCEDURES SOI 1	2,454	20,458	16,424	0.89388	80.28
037	OTHER NERVOUS SYSTEM & RELATED PROCEDURES SOI 2	3,675	33,352	24,756	1.45728	74.23
038	OTHER NERVOUS SYSTEM & RELATED PROCEDURES SOI 3	2,926	53,577	42,702	2.34097	79.70
039	NERVOUS SYSTEM MEDICAL DIAGNOSES EXCEPT INFECTIONS SOI 4	30,386	47,223	50,796	2.06336	107.56
040	INFECTIONS OF NERVOUS SYSTEM SOI 4	1,357	77,412	64,271	3.38243	83.02
041	SPINAL DISORDERS & INJURIES SOI 1	326	12,721	13,139	0.55583	103.28
042	SPINAL DISORDERS & INJURIES SOI 2	1,394	17,140	16,704	0.74891	97.46
043	SPINAL DISORDERS & INJURIES SOI 3	817	28,179	29,762	1.23124	105.62
044	NERVOUS SYSTEM MALIGNANCY SOI 1	1,565	13,042	10,784	0.56986	82.69
045	NERVOUS SYSTEM MALIGNANCY SOI 2	8,648	15,185	14,186	0.66349	93.42
046	NERVOUS SYSTEM MALIGNANCY SOI 3	7,652	22,708	20,839	0.99218	91.77
047	DEGENERATIVE NERV SYS DISORDERS EXC MULT SCLEROSIS SOI 1	6,399	9,678	10,474	0.42285	108.23
048	DEGENERATIVE NERV SYS DISORDERS EXC MULT SCLEROSIS SOI 2	27,688	11,657	11,474	0.50934	98.43
049	DEGENERATIVE NERV SYS DISORDERS EXC MULT SCLEROSIS SOI 3	10,258	18,399	20,213	0.80394	109.86
050	MULTIPLE SCLEROSIS & OTHER DEMYELINATING DISEASES SOI 1	2,767	11,622	12,643	0.50779	108.79
051	MULTIPLE SCLEROSIS & OTHER DEMYELINATING DISEASES SOI 2	4,086	15,305	16,585	0.66872	108.36
052	MULTIPLE SCLEROSIS & OTHER DEMYELINATING DISEASES SOI 3	891	24,315	25,790	1.06241	106.07
053	INTRACRANIAL HEMORRHAGE SOI 1	7,992	11,639	11,189	0.50854	96.13
054	INTRACRANIAL HEMORRHAGE SOI 2	13,919	15,686	15,053	0.68537	95.97
055	INTRACRANIAL HEMORRHAGE SOI 3	17,303	20,640	21,917	0.90185	106.18
056	CVA & PRECEREBRAL OCCLUSION W INFARCT SOI 1	18,595	12,388	9,824	0.54129	79.30
057	CVA & PRECEREBRAL OCCLUSION W INFARCT SOI 2	104,700	15,473	11,886	0.67606	76.82
058	CVA & PRECEREBRAL OCCLUSION W INFARCT SOI 3	55,390	23,141	21,025	1.01112	90.86
059	NONSPECIFIC CVA & PRECEREBRAL OCCLUSION W/O INFARCT SOI 1	9,671	10,296	7,669	0.44989	74.49
060	NONSPECIFIC CVA & PRECEREBRAL OCCLUSION W/O INFARCT SOI 2	44,930	12,761	10,139	0.55757	79.45
061	NONSPECIFIC CVA & PRECEREBRAL OCCLUSION W/O INFARCT SOI 3	18,505	18,302	17,676	0.79968	96.58
062	TRANSIENT ISCHEMIA SOI 1	26,515	9,480	6,827	0.41423	72.01
063	TRANSIENT ISCHEMIA SOI 2	72,653	11,208	8,803	0.48973	78.54
064	TRANSIENT ISCHEMIA SOI 3	17,220	15,025	13,669	0.65651	90.98
065	PERIPHERAL, CRANIAL & AUTONOMIC NERVE DISORDERS SOI 1	8,107	10,591	10,801	0.46278	101.98
066	PERIPHERAL, CRANIAL & AUTONOMIC NERVE DISORDERS SOI 2	19,967	12,960	11,903	0.56627	91.85
067	PERIPHERAL, CRANIAL & AUTONOMIC NERVE DISORDERS SOI 3	11,626	18,278	19,703	0.79862	107.80
068	BACTERIAL & TUBERCULOUS INFECTIONS OF NERVOUS SYSTEM SOI 1	92	17,994	12,838	0.78622	71.34
069	BACTERIAL & TUBERCULOUS INFECTIONS OF NERVOUS SYSTEM SOI 2	1,454	31,547	30,183	1.37841	95.68
070	BACTERIAL & TUBERCULOUS INFECTIONS OF NERVOUS SYSTEM SOI 3	1,266	42,597	36,479	1.86121	85.64
071	NON-BACTERIAL INFECTIONS OF NERV SYS EXC VIRAL MENINGITIS SOI 1	1,682	11,521	11,666	0.50339	101.26
072	NON-BACTERIAL INFECTIONS OF NERV SYS EXC VIRAL MENINGITIS SOI 2	1,904	22,270	23,479	0.97306	105.43
073	NON-BACTERIAL INFECTIONS OF NERV SYS EXC VIRAL MENINGITIS SOI 3	1,522	36,807	37,768	1.60822	102.61
074	VIRAL MENINGITIS SOI 1	398	11,962	8,549	0.52265	71.47

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
075	VIRAL MENINGITIS SOI 2	1,013	17,244	14,531	0.75345	84.27
076	VIRAL MENINGITIS SOI 3	509	28,222	21,766	1.23312	77.12
077	NONTRAUMATIC STUPOR & COMA SOI 1	3,603	9,219	6,827	0.40281	74.05
078	NONTRAUMATIC STUPOR & COMA SOI 2	9,460	11,568	10,495	0.50546	90.72
079	NONTRAUMATIC STUPOR & COMA SOI 3	19,354	19,216	18,808	0.83963	97.88
080	SEIZURE SOI 1	13,839	9,064	8,479	0.39603	93.55
081	SEIZURE SOI 2	38,538	11,791	10,688	0.51518	90.65
082	SEIZURE SOI 3	19,044	18,583	19,029	0.81195	102.40
083	MIGRAINE & OTHER HEADACHES SOI 1	5,019	8,799	6,702	0.38446	76.16
084	MIGRAINE & OTHER HEADACHES SOI 2	9,527	10,676	8,586	0.46646	80.42
085	MIGRAINE & OTHER HEADACHES SOI 3	1,879	14,898	13,564	0.65096	91.05
086	HEAD TRAUMA W COMA >1 HR OR HEMORRHAGE SOI 1	3,351	10,685	10,755	0.46685	100.66
087	HEAD TRAUMA W COMA >1 HR OR HEMORRHAGE SOI 2	10,731	15,274	15,086	0.66740	98.77
088	HEAD TRAUMA W COMA >1 HR OR HEMORRHAGE SOI 3	6,249	21,485	22,355	0.93878	104.05
089	BRAIN CONTUSION/LACERATION & COMP SKULL FX, COMA < 1 HR OR NO COMA SOI 1	851	10,282	9,591	0.44925	93.28
090	BRAIN CONTUSION/LACERATION & COMP SKULL FX, COMA < 1 HR OR NO COMA SOI 2	2,732	15,561	14,333	0.67992	92.11
091	BRAIN CONTUSION/LACERATION & COMP SKULL FX, COMA < 1 HR OR NO COMA SOI 3	1,159	25,361	25,994	1.10811	102.50
092	CONCUSSION, CL SKULL FX NOS,UNCOMP INTRACRAN INJ, COMA < 1 HR OR NONE	1,893	9,896	7,972	0.43241	80.56
093	CONCUSSION, CL SKULL FX NOS,UNCOMP INTRACRAN INJ, COMA < 1 HR OR NONE	5,341	12,282	10,175	0.53663	82.84
094	CONCUSSION, CL SKULL FX NOS,UNCOMP INTRACRAN INJ, COMA < 1 HR OR NONE	1,697	20,393	22,173	0.89105	108.73
095	OTHER DISORDERS OF NERVOUS SYSTEM SOI 1	20,944	10,366	8,785	0.45294	84.75
096	OTHER DISORDERS OF NERVOUS SYSTEM SOI 2	17,790	13,113	11,753	0.57296	89.63
097	OTHER DISORDERS OF NERVOUS SYSTEM SOI 3	6,179	19,720	20,921	0.86163	106.09
098	EYE PROCEDURES SOI 4	47	71,606	53,620	3.12872	74.88
099	ORBITAL PROCEDURES SOI 1	358	11,831	8,661	0.51696	73.20
100	ORBITAL PROCEDURES SOI 2	613	17,609	15,370	0.76940	87.29
101	ORBITAL PROCEDURES SOI 3	207	27,041	26,652	1.18154	98.56
102	EYE PROCEDURES EXCEPT ORBIT SOI 1	1,895	10,977	6,569	0.47961	59.84
103	EYE PROCEDURES EXCEPT ORBIT SOI 2	1,897	12,683	8,682	0.55415	68.45
104	EYE PROCEDURES EXCEPT ORBIT SOI 3	241	23,544	23,572	1.02872	100.12
105	EYE DIAGNOSES SOI 4	71	51,833	78,197	2.26477	150.86
106	ACUTE MAJOR EYE INFECTIONS SOI 1	341	7,888	8,130	0.34465	103.07
107	ACUTE MAJOR EYE INFECTIONS SOI 2	1,544	10,955	10,300	0.47867	94.02
108	ACUTE MAJOR EYE INFECTIONS SOI 3	404	17,770	19,385	0.77644	109.09
109	EYE DISORDERS EXCEPT MAJOR INFECTIONS SOI 1	1,474	8,301	7,114	0.36270	85.70
110	EYE DISORDERS EXCEPT MAJOR INFECTIONS SOI 2	3,778	10,703	9,533	0.46767	89.06
111	EYE DISORDERS EXCEPT MAJOR INFECTIONS SOI 3	952	14,165	12,558	0.61893	88.65
112	EAR, NOSE, MOUTH & THROAT PROCEDURES SOI 4	596	83,604	77,513	3.65296	92.71
113	MAJOR CRANIAL/FACIAL BONE PROCEDURES SOI 1	268	20,198	14,544	0.88253	72.01

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
114	MAJOR CRANIAL/FACIAL BONE PROCEDURES SOI 2	607	27,968	22,836	1.22203	81.65
115	MAJOR CRANIAL/FACIAL BONE PROCEDURES SOI 3	796	52,764	50,632	2.30546	95.96
116	MAJOR LARYNX & TRACHEA PROCEDURES SOI 1	45	11,068	8,848	0.48361	79.94
117	MAJOR LARYNX & TRACHEA PROCEDURES SOI 2	1,120	39,328	35,321	1.71839	89.81
118	MAJOR LARYNX & TRACHEA PROCEDURES SOI 3	318	67,548	61,822	2.95141	91.52
119	OTHER MAJOR HEAD & NECK PROCEDURES SOI 1	1,025	21,205	17,167	0.92652	80.96
120	OTHER MAJOR HEAD & NECK PROCEDURES SOI 2	1,201	33,119	29,934	1.44709	90.38
121	OTHER MAJOR HEAD & NECK PROCEDURES SOI 3	259	57,660	49,988	2.51937	86.69
122	FACIAL BONE PROCEDURES EXCEPT MAJOR CRANIAL/FACIAL BONE PROCS SOI 1	611	15,285	12,391	0.66785	81.07
123	FACIAL BONE PROCEDURES EXCEPT MAJOR CRANIAL/FACIAL BONE PROCS SOI 2	855	20,396	14,799	0.89116	72.56
124	FACIAL BONE PROCEDURES EXCEPT MAJOR CRANIAL/FACIAL BONE PROCS SOI 3	340	35,774	30,365	1.56311	84.88
125	SINUS & MASTOID PROCEDURES SOI 1	938	13,087	9,069	0.57180	69.30
126	SINUS & MASTOID PROCEDURES SOI 2	919	19,474	16,265	0.85089	83.52
127	SINUS & MASTOID PROCEDURES SOI 3	222	37,558	35,710	1.64107	95.08
128	CLEFT LIP & PALATE REPAIR SOI 1	454	10,912	6,311	0.47681	57.83
129	CLEFT LIP & PALATE REPAIR SOI 2	202	13,547	10,787	0.59191	79.63
130	CLEFT LIP & PALATE REPAIR SOI 3	29	35,498	29,726	1.55103	83.74
131	TONSIL & ADENOID PROCEDURES SOI 1	232	10,634	11,766	0.46466	110.64
132	TONSIL & ADENOID PROCEDURES SOI 2	354	16,989	16,101	0.74230	94.78
133	TONSIL & ADENOID PROCEDURES SOI 3	106	38,094	35,685	1.66445	93.68
134	OTHER EAR, NOSE, MOUTH & THROAT PROCEDURES SOI 1	3,726	12,246	11,216	0.53507	91.59
135	OTHER EAR, NOSE, MOUTH & THROAT PROCEDURES SOI 2	3,641	16,922	15,629	0.73938	92.36
136	OTHER EAR, NOSE, MOUTH & THROAT PROCEDURES SOI 3	979	35,124	37,395	1.53468	106.47
137	EAR, NOSE, MOUTH & THROAT DIAGNOSES SOI 4	1,730	44,302	61,598	1.93570	139.04
138	EAR, NOSE, MOUTH, THROAT, CRANIAL/FACIAL MALIGNANCIES SOI 1	354	9,385	8,762	0.41008	93.36
139	EAR, NOSE, MOUTH, THROAT, CRANIAL/FACIAL MALIGNANCIES SOI 2	1,478	12,876	13,400	0.56261	104.07
140	EAR, NOSE, MOUTH, THROAT, CRANIAL/FACIAL MALIGNANCIES SOI 3	1,865	23,453	27,394	1.02476	116.80
141	VERTIGO & OTHER LABYRINTH DISORDERS SOI 1	14,310	8,263	6,251	0.36106	75.65
142	VERTIGO & OTHER LABYRINTH DISORDERS SOI 2	22,904	9,742	7,783	0.42564	79.90
143	VERTIGO & OTHER LABYRINTH DISORDERS SOI 3	3,525	12,453	11,599	0.54413	93.14
144	INFECTIONS OF UPPER RESPIRATORY TRACT SOI 1	2,908	6,774	5,196	0.29600	76.70
145	INFECTIONS OF UPPER RESPIRATORY TRACT SOI 2	14,630	8,831	7,597	0.38585	86.03
146	INFECTIONS OF UPPER RESPIRATORY TRACT SOI 3	5,012	13,792	14,170	0.60263	102.74
147	DENTAL & ORAL DISEASES & INJURIES SOI 1	1,116	8,016	7,360	0.35025	91.81
148	DENTAL & ORAL DISEASES & INJURIES SOI 2	3,410	11,164	10,057	0.48781	90.09
149	DENTAL & ORAL DISEASES & INJURIES SOI 3	1,613	19,656	21,416	0.85882	108.96
150	OTHER EAR, NOSE, MOUTH,THROAT & CRANIAL/FACIAL DIAGNOSES SOI 1	9,240	8,118	8,255	0.35472	101.68
151	OTHER EAR, NOSE, MOUTH,THROAT & CRANIAL/FACIAL DIAGNOSES SOI 2	9,320	11,569	11,003	0.50550	95.11
152	OTHER EAR, NOSE, MOUTH,THROAT & CRANIAL/FACIAL DIAGNOSES SOI 3	3,322	17,305	19,287	0.75610	111.45

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
153	RESPIRATORY & CHEST PROCEDURES SOI 4	5,287	115,874	105,081	5.06296	90.69
154	MAJOR RESPIRATORY & CHEST PROCEDURES SOI 1	4,742	30,170	18,063	1.31825	59.87
155	MAJOR RESPIRATORY & CHEST PROCEDURES SOI 2	12,210	39,251	25,338	1.71504	64.55
156	MAJOR RESPIRATORY & CHEST PROCEDURES SOI 3	5,804	63,392	49,865	2.76983	78.66
157	OTHER RESPIRATORY & CHEST PROCEDURES SOI 1	5,502	20,708	14,374	0.90481	69.41
158	OTHER RESPIRATORY & CHEST PROCEDURES SOI 2	12,553	30,302	24,750	1.32403	81.68
159	OTHER RESPIRATORY & CHEST PROCEDURES SOI 3	6,765	52,665	45,274	2.30112	85.97
160	RESPIRATORY SYSTEM DX EXCEPT W VENTILATOR SUPPORT 96+ HOURS SOI 4	134,101	37,710	40,877	1.64770	108.40
161	RESPIRATORY SYSTEM DX W VENTILATOR SUPPORT 96+ HOURS SOI 1	577	49,225	36,264	2.15081	73.67
162	RESPIRATORY SYSTEM DX W VENTILATOR SUPPORT 96+ HOURS SOI 2	4,729	58,938	49,398	2.57520	83.81
163	RESPIRATORY SYSTEM DX W VENTILATOR SUPPORT 96+ HOURS SOI 3	17,232	77,296	80,500	3.37735	104.14
164	RESPIRATORY SYSTEM DX W VENTILATOR SUPPORT 96+ HOURS SOI 4	25,435	94,910	86,662	4.14695	91.31
165	CYSTIC FIBROSIS - PULMONARY DISEASE SOI 1	96	21,544	23,523	0.94135	109.18
166	CYSTIC FIBROSIS - PULMONARY DISEASE SOI 2	642	25,119	27,263	1.09755	108.54
167	CYSTIC FIBROSIS - PULMONARY DISEASE SOI 3	896	30,017	27,835	1.31156	92.73
168	PULMONARY EDEMA & RESPIRATORY FAILURE SOI 1	1,260	9,283	7,726	0.40562	83.22
169	PULMONARY EDEMA & RESPIRATORY FAILURE SOI 2	21,832	15,578	15,205	0.68065	97.60
170	PULMONARY EDEMA & RESPIRATORY FAILURE SOI 3	49,498	22,363	20,474	0.97711	91.55
171	PULMONARY EMBOLISM SOI 1	7,578	14,895	10,784	0.65082	72.40
172	PULMONARY EMBOLISM SOI 2	25,154	18,669	14,228	0.81574	76.21
173	PULMONARY EMBOLISM SOI 3	17,872	26,253	22,188	1.14707	84.52
174	MAJOR CHEST & RESPIRATORY TRAUMA SOI 1	4,587	10,715	9,282	0.46816	86.63
175	MAJOR CHEST & RESPIRATORY TRAUMA SOI 2	5,164	14,173	12,504	0.61929	88.22
176	MAJOR CHEST & RESPIRATORY TRAUMA SOI 3	3,746	22,098	19,025	0.96555	86.09
177	RESPIRATORY MALIGNANCY SOI 1	3,140	11,847	10,363	0.51766	87.47
178	RESPIRATORY MALIGNANCY SOI 2	28,254	16,475	15,047	0.71984	91.34
179	RESPIRATORY MALIGNANCY SOI 3	36,426	26,644	25,070	1.16419	94.09
180	MAJOR RESPIRATORY INFECTIONS & INFLAMMATIONS SOI 1	6,516	13,048	12,260	0.57011	93.96
181	MAJOR RESPIRATORY INFECTIONS & INFLAMMATIONS SOI 2	64,323	17,393	16,861	0.75998	96.94
182	MAJOR RESPIRATORY INFECTIONS & INFLAMMATIONS SOI 3	89,638	25,930	25,445	1.13296	98.13
183	BRONCHIOLITIS & RSV PNEUMONIA SOI 1	51	8,416	6,497	0.36772	77.20
184	BRONCHIOLITIS & RSV PNEUMONIA SOI 2	249	11,369	11,634	0.49674	102.34
185	BRONCHIOLITIS & RSV PNEUMONIA SOI 3	145	21,114	20,156	0.92254	95.46
186	OTHER PNEUMONIA SOI 1	32,846	9,081	7,499	0.39678	82.57
187	OTHER PNEUMONIA SOI 2	303,536	12,561	10,897	0.54885	86.75
188	OTHER PNEUMONIA SOI 3	230,861	19,100	18,409	0.83454	96.38
189	CHRONIC OBSTRUCTIVE PULMONARY DISEASE SOI 1	99,711	9,971	8,617	0.43566	86.43
190	CHRONIC OBSTRUCTIVE PULMONARY DISEASE SOI 2	201,721	12,670	11,212	0.55359	88.49
191	CHRONIC OBSTRUCTIVE PULMONARY DISEASE SOI 3	99,558	18,146	17,664	0.79285	97.34

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
192	ASTHMA SOI 1	10,558	8,019	6,600	0.35038	82.30
193	ASTHMA SOI 2	21,869	10,472	9,629	0.45755	91.95
194	ASTHMA SOI 3	5,591	15,625	15,215	0.68273	97.38
195	INTERSTITIAL LUNG DISEASE SOI 1	1,136	11,561	10,798	0.50516	93.39
196	INTERSTITIAL LUNG DISEASE SOI 2	8,708	14,835	12,758	0.64820	86.00
197	INTERSTITIAL LUNG DISEASE SOI 3	8,249	20,807	18,142	0.90913	87.19
198	OTHER RESPIRATORY DXS EXCEPT SIGNS, SYMPTOMS & MINOR DIAGNOSES SOI 1	4,431	9,334	7,763	0.40785	83.16
199	OTHER RESPIRATORY DXS EXCEPT SIGNS, SYMPTOMS & MINOR DIAGNOSES SOI 2	23,229	13,339	12,684	0.58283	95.09
200	OTHER RESPIRATORY DXS EXCEPT SIGNS, SYMPTOMS & MINOR DIAGNOSES SOI 3	14,048	20,303	20,605	0.88710	101.49
201	RESPIRATORY SIGNS, SYMPTOMS & MINOR DIAGNOSES SOI 1	23,832	8,418	6,761	0.36780	80.32
202	RESPIRATORY SIGNS, SYMPTOMS & MINOR DIAGNOSES SOI 2	45,712	10,181	8,919	0.44484	87.61
203	RESPIRATORY SIGNS, SYMPTOMS & MINOR DIAGNOSES SOI 3	17,048	14,356	13,630	0.62727	94.94
204	CARDIOTHORACIC PROCEDURES SOI 4	22,977	160,063	116,591	6.99374	72.84
205	VASCULAR PROCEDURES SOI 4	13,100	107,242	91,715	4.68582	85.52
206	OTHER CIRCULATORY SYSTEM PROCEDURES SOI 4	21,049	83,691	65,081	3.65678	77.76
207	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 1	5,898	74,119	36,020	3.23853	48.60
208	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 2	23,739	84,460	41,653	3.69037	49.32
209	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 3	27,378	102,304	53,208	4.47002	52.01
210	CARDIAC VALVE PROCEDURES W CARDIAC CATHETERIZATION SOI 1	1,168	78,422	41,656	3.42657	53.12
211	CARDIAC VALVE PROCEDURES W CARDIAC CATHETERIZATION SOI 2	4,515	88,689	44,213	3.87513	49.85
212	CARDIAC VALVE PROCEDURES W CARDIAC CATHETERIZATION SOI 3	9,731	117,445	67,363	5.13160	57.36
213	CARDIAC VALVE PROCEDURES W/O CARDIAC CATHETERIZATION SOI 1	3,303	62,542	33,559	2.73268	53.66
214	CARDIAC VALVE PROCEDURES W/O CARDIAC CATHETERIZATION SOI 2	10,084	70,290	34,834	3.07123	49.56
215	CARDIAC VALVE PROCEDURES W/O CARDIAC CATHETERIZATION SOI 3	12,471	93,128	56,661	4.06909	60.84
216	CORONARY BYPASS W CARDIAC CATH OR PERC CARDIAC PROC SOI 1	5,336	60,512	28,115	2.64401	46.46
217	CORONARY BYPASS W CARDIAC CATH OR PERC CARDIAC PROC SOI 2	37,298	70,325	34,957	3.07278	49.71
218	CORONARY BYPASS W CARDIAC CATH OR PERC CARDIAC PROC SOI 3	26,026	92,578	51,594	4.04507	55.73
219	CORONARY BYPASS W/O CARDIAC CATH OR PERC CARDIAC PROC SOI 1	5,877	47,148	23,482	2.06005	49.80
220	CORONARY BYPASS W/O CARDIAC CATH OR PERC CARDIAC PROC SOI 2	30,027	53,797	27,692	2.35060	51.48
221	CORONARY BYPASS W/O CARDIAC CATH OR PERC CARDIAC PROC SOI 3	14,525	73,563	56,721	3.21424	77.11
222	OTHER CARDIOTHORACIC PROCEDURES SOI 1	547	44,784	30,732	1.95678	68.62
223	OTHER CARDIOTHORACIC PROCEDURES SOI 2	747	53,996	34,269	2.35928	63.47
224	OTHER CARDIOTHORACIC PROCEDURES SOI 3	1,668	83,099	56,553	3.63088	68.05
225	MAJOR THORACIC & ABDOMINAL VASCULAR PROCEDURES SOI 1	3,404	30,901	22,454	1.35019	72.66
226	MAJOR THORACIC & ABDOMINAL VASCULAR PROCEDURES SOI 2	14,372	40,260	27,338	1.75912	67.90
227	MAJOR THORACIC & ABDOMINAL VASCULAR PROCEDURES SOI 3	11,135	58,739	46,342	2.56651	78.89
228	PERMANENT CARDIAC PACEMAKER IMPLANT W AMI, HEART FAILURE OR SHOCK SOI 1	1,430	42,248	24,158	1.84599	57.18
229	PERMANENT CARDIAC PACEMAKER IMPLANT W AMI, HEART FAILURE OR SHOCK SOI 2	7,948	48,274	28,715	2.10928	59.48
230	PERMANENT CARDIAC PACEMAKER IMPLANT W AMI, HEART FAILURE OR SHOCK SOI 3	4,275	62,572	46,083	2.73402	73.65

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
231	PERM CARDIAC PACEMAKER IMPLANT W/O AMI, HEART FAILURE OR SHOCK SOI 1	40,070	28,793	14,799	1.25808	51.40
232	PERM CARDIAC PACEMAKER IMPLANT W/O AMI, HEART FAILURE OR SHOCK SOI 2	55,647	34,868	19,590	1.52352	56.18
233	PERM CARDIAC PACEMAKER IMPLANT W/O AMI, HEART FAILURE OR SHOCK SOI 3	14,104	48,392	32,548	2.11442	67.26
234	OTHER VASCULAR PROCEDURES SOI 1	37,399	27,261	19,497	1.19115	71.52
235	OTHER VASCULAR PROCEDURES SOI 2	52,116	33,343	25,233	1.45686	75.68
236	OTHER VASCULAR PROCEDURES SOI 3	32,283	51,869	42,400	2.26634	81.74
237	PERCUTANEOUS CARDIOVASCULAR PROCEDURES W AMI SOI 1	24,064	36,428	18,607	1.59167	51.08
238	PERCUTANEOUS CARDIOVASCULAR PROCEDURES W AMI SOI 2	47,032	40,823	22,098	1.78370	54.13
239	PERCUTANEOUS CARDIOVASCULAR PROCEDURES W AMI SOI 3	18,252	53,355	31,919	2.33128	59.82
240	PERCUTANEOUS CARDIOVASCULAR PROCEDURES W/O AMI SOI 1	147,569	31,371	16,373	1.37069	52.19
241	PERCUTANEOUS CARDIOVASCULAR PROCEDURES W/O AMI SOI 2	110,820	35,053	19,780	1.53158	56.43
242	PERCUTANEOUS CARDIOVASCULAR PROCEDURES W/O AMI SOI 3	33,126	47,305	30,907	2.06691	65.34
243	CARDIAC PACEMAKER & DEFIBRILLATOR DEVICE REPLACEMENT SOI 1	6,453	23,357	13,823	1.02056	59.18
244	CARDIAC PACEMAKER & DEFIBRILLATOR DEVICE REPLACEMENT SOI 2	1,258	45,812	27,259	2.00170	59.50
245	CARDIAC PACEMAKER & DEFIBRILLATOR DEVICE REPLACEMENT SOI 3	3,560	53,618	30,769	2.34277	57.39
246	CARDIAC PACEMAKER & DEFIBRILLATOR REVISION EXC DEVICE REPLACEMENT SOI 1	3,419	14,754	13,646	0.64464	92.49
247	CARDIAC PACEMAKER & DEFIBRILLATOR REVISION EXC DEVICE REPLACEMENT SOI 2	2,012	26,821	24,423	1.17193	91.06
248	CARDIAC PACEMAKER & DEFIBRILLATOR REVISION EXC DEVICE REPLACEMENT SOI 3	1,254	43,667	36,884	1.90797	84.47
249	OTHER CIRCULATORY SYSTEM PROCEDURES SOI 1	1,645	18,303	16,458	0.79972	89.92
250	OTHER CIRCULATORY SYSTEM PROCEDURES SOI 2	4,361	27,229	24,786	1.18975	91.03
251	OTHER CIRCULATORY SYSTEM PROCEDURES SOI 3	7,986	47,032	46,717	2.05501	99.33
252	CIRCULATORY SYSTEM DIAGNOSES SOI 4	102,283	42,903	49,723	1.87461	115.89
253	ACUTE MYOCARDIAL INFARCTION SOI 1	31,339	12,113	10,020	0.52926	82.73
254	ACUTE MYOCARDIAL INFARCTION SOI 2	87,248	16,004	13,284	0.69927	83.00
255	ACUTE MYOCARDIAL INFARCTION SOI 3	70,868	22,806	19,731	0.99646	86.52
256	CARDIAC CATHETERIZATION W CIRC DISORD EXC ISCHEMIC HEART DISEASE SOI 1	11,410	17,455	10,806	0.76269	61.90
257	CARDIAC CATHETERIZATION W CIRC DISORD EXC ISCHEMIC HEART DISEASE SOI 2	19,737	21,016	14,489	0.91827	68.94
258	CARDIAC CATHETERIZATION W CIRC DISORD EXC ISCHEMIC HEART DISEASE SOI 3	42,954	28,233	22,628	1.23361	80.15
259	CARDIAC CATHETERIZATION FOR ISCHEMIC HEART DISEASE SOI 1	64,562	15,036	8,655	0.65699	57.56
260	CARDIAC CATHETERIZATION FOR ISCHEMIC HEART DISEASE SOI 2	74,623	17,696	11,121	0.77320	62.85
261	CARDIAC CATHETERIZATION FOR ISCHEMIC HEART DISEASE SOI 3	18,443	23,576	17,091	1.03011	72.49
262	ACUTE & SUBACUTE ENDOCARDITIS SOI 1	216	18,973	16,174	0.82898	85.25
263	ACUTE & SUBACUTE ENDOCARDITIS SOI 2	1,430	25,279	22,148	1.10453	87.61
264	ACUTE & SUBACUTE ENDOCARDITIS SOI 3	2,883	39,865	38,341	1.74186	96.18
265	HEART FAILURE SOI 1	82,001	9,791	8,380	0.42781	85.59
266	HEART FAILURE SOI 2	419,189	13,399	12,111	0.58545	90.39
267	HEART FAILURE SOI 3	177,648	21,516	21,094	0.94012	98.04
268	CARDIAC ARREST SOI 1	264	6,927	9,899	0.30265	142.91
269	CARDIAC ARREST SOI 2	1,190	8,970	8,859	0.39194	98.76

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
270	CARDIAC ARREST SOI 3	2,540	13,805	14,928	0.60319	108.14
271	PERIPHERAL & OTHER VASCULAR DISORDERS SOI 1	29,057	9,071	8,466	0.39636	93.33
272	PERIPHERAL & OTHER VASCULAR DISORDERS SOI 2	62,960	12,606	12,163	0.55080	96.49
273	PERIPHERAL & OTHER VASCULAR DISORDERS SOI 3	34,884	19,448	19,890	0.84977	102.27
274	ANGINA PECTORIS & CORONARY ATHEROSCLEROSIS SOI 1	95,559	7,596	5,959	0.33191	78.45
275	ANGINA PECTORIS & CORONARY ATHEROSCLEROSIS SOI 2	135,482	9,215	7,634	0.40265	82.83
276	ANGINA PECTORIS & CORONARY ATHEROSCLEROSIS SOI 3	32,337	12,612	11,985	0.55105	95.03
277	HYPERTENSION SOI 1	14,746	7,416	6,192	0.32403	83.50
278	HYPERTENSION SOI 2	22,139	9,617	8,356	0.42020	86.88
279	HYPERTENSION SOI 3	4,850	14,336	13,481	0.62641	94.03
280	CARDIAC STRUCTURAL & VALVULAR DISORDERS SOI 1	1,108	9,465	8,546	0.41357	90.28
281	CARDIAC STRUCTURAL & VALVULAR DISORDERS SOI 2	4,185	10,975	9,949	0.47953	90.66
282	CARDIAC STRUCTURAL & VALVULAR DISORDERS SOI 3	2,806	16,256	17,833	0.71029	109.70
283	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS SOI 1	71,154	8,011	6,609	0.35004	82.50
284	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS SOI 2	142,201	10,655	9,380	0.46555	88.03
285	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS SOI 3	59,889	15,872	15,858	0.69350	99.91
286	CHEST PAIN SOI 1	64,784	7,811	5,530	0.34129	70.80
287	CHEST PAIN SOI 2	69,732	9,399	7,368	0.41069	78.38
288	CHEST PAIN SOI 3	12,711	12,870	11,731	0.56234	91.15
289	SYNCOPE & COLLAPSE SOI 1	40,826	8,928	6,903	0.39010	77.32
290	SYNCOPE & COLLAPSE SOI 2	98,132	11,079	9,084	0.48410	81.99
291	SYNCOPE & COLLAPSE SOI 3	24,449	15,003	14,358	0.65556	95.70
292	CARDIOMYOPATHY SOI 1	469	9,771	10,110	0.42695	103.47
293	CARDIOMYOPATHY SOI 2	1,851	11,460	10,505	0.50075	91.66
294	CARDIOMYOPATHY SOI 3	1,550	16,827	16,202	0.73525	96.29
295	MALFUNCTION,REACTION,COMPLICATION OF CARDIAC/VASC DEVICE OR PROC SOI 1	1,817	10,112	11,666	0.44184	115.37
296	MALFUNCTION,REACTION,COMPLICATION OF CARDIAC/VASC DEVICE OR PROCSOI 2	12,122	13,447	14,216	0.58753	105.72
297	MALFUNCTION,REACTION,COMPLICATION OF CARDIAC/VASC DEVICE OR PROCSOI 3	13,240	24,665	26,110	1.07771	105.86
298	OTHER CIRCULATORY SYSTEM DIAGNOSES SOI 1	20,381	9,331	8,539	0.40771	91.51
299	OTHER CIRCULATORY SYSTEM DIAGNOSES SOI 2	17,789	13,772	13,350	0.60175	96.94
300	OTHER CIRCULATORY SYSTEM DIAGNOSES SOI 3	8,541	19,771	21,349	0.86387	107.98
301	MAJOR GASTROINTESTINAL PROCEDURES SOI 4	29,082	109,482	102,322	4.78369	93.46
302	OTHER GASTROINTESTINAL & ABDOMINAL PROCEDURES SOI 4	5,428	85,624	79,026	3.74122	92.29
303	MAJOR STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES SOI 1	8,881	22,214	16,751	0.97062	75.41
304	MAJOR STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES SOI 2	8,076	40,950	34,748	1.78927	84.86
305	MAJOR STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES SOI 3	8,123	65,975	58,505	2.88270	88.68
306	MAJOR SMALL & LARGE BOWEL PROCEDURES SOI 1	30,740	22,994	14,572	1.00470	63.37
307	MAJOR SMALL & LARGE BOWEL PROCEDURES SOI 2	65,436	33,715	25,600	1.47313	75.93
308	MAJOR SMALL & LARGE BOWEL PROCEDURES SOI 3	44,150	58,599	49,374	2.56042	84.26

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
309	OTHER STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES SOI 1	703	15,771	13,523	0.68907	85.75
310	OTHER STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES SOI 2	1,204	25,685	23,209	1.12227	90.36
311	OTHER STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES SOI 3	607	48,567	41,548	2.12208	85.55
312	OTHER SMALL & LARGE BOWEL PROCEDURES SOI 1	5,840	19,365	15,169	0.84614	78.33
313	OTHER SMALL & LARGE BOWEL PROCEDURES SOI 2	6,814	27,348	21,858	1.19494	79.93
314	OTHER SMALL & LARGE BOWEL PROCEDURES SOI 3	3,965	47,383	41,308	2.07035	87.18
315	PERITONEAL ADHESIOLYSIS SOI 1	3,002	22,339	17,635	0.97607	78.94
316	PERITONEAL ADHESIOLYSIS SOI 2	5,911	33,058	22,834	1.44442	69.07
317	PERITONEAL ADHESIOLYSIS SOI 3	3,867	50,452	40,739	2.20443	80.75
318	APPENDECTOMY SOI 1	4,692	14,117	7,969	0.61681	56.45
319	APPENDECTOMY SOI 2	10,584	21,633	15,097	0.94522	69.79
320	APPENDECTOMY SOI 3	2,713	39,674	32,367	1.73348	81.58
321	ANAL PROCEDURES SOI 1	5,499	11,011	9,586	0.48109	87.06
322	ANAL PROCEDURES SOI 2	3,246	16,789	25,907	0.73358	154.31
323	ANAL PROCEDURES SOI 3	838	30,227	27,793	1.32071	91.95
324	HERNIA PROCEDURES EXCEPT INGUINAL, FEMORAL & UMBILICAL SOI 1	14,360	14,319	9,238	0.62564	64.52
325	HERNIA PROCEDURES EXCEPT INGUINAL, FEMORAL & UMBILICAL SOI 2	15,844	20,253	16,068	0.88493	79.33
326	HERNIA PROCEDURES EXCEPT INGUINAL, FEMORAL & UMBILICAL SOI 3	3,745	39,262	34,839	1.71552	88.73
327	INGUINAL, FEMORAL & UMBILICAL HERNIA PROCEDURES SOI 1	7,506	10,947	7,451	0.47830	68.06
328	INGUINAL, FEMORAL & UMBILICAL HERNIA PROCEDURES SOI 2	9,625	16,056	13,564	0.70154	84.48
329	INGUINAL, FEMORAL & UMBILICAL HERNIA PROCEDURES SOI 3	2,613	30,956	29,326	1.35259	94.73
330	OTHER DIGESTIVE SYSTEM & ABDOMINAL PROCEDURES SOI 1	1,611	20,040	17,082	0.87563	85.24
331	OTHER DIGESTIVE SYSTEM & ABDOMINAL PROCEDURES SOI 2	4,762	28,934	23,310	1.26424	80.56
332	OTHER DIGESTIVE SYSTEM & ABDOMINAL PROCEDURES SOI 3	3,944	51,819	53,693	2.26415	103.62
333	DIGESTIVE SYSTEM DIAGNOSES SOI 4	31,660	44,635	53,249	1.95025	119.30
334	DIGESTIVE MALIGNANCY SOI 1	2,253	11,315	10,450	0.49441	92.36
335	DIGESTIVE MALIGNANCY SOI 2	13,819	15,141	14,506	0.66157	95.81
336	DIGESTIVE MALIGNANCY SOI 3	14,662	25,379	27,421	1.10890	108.05
337	PEPTIC ULCER & GASTRITIS SOI 1	23,189	9,702	7,783	0.42394	80.22
338	PEPTIC ULCER & GASTRITIS SOI 2	70,969	12,933	10,192	0.56508	78.81
339	PEPTIC ULCER & GASTRITIS SOI 3	42,974	19,912	18,082	0.87001	90.81
340	MAJOR ESOPHAGEAL DISORDERS SOI 1	731	9,805	11,502	0.42843	117.31
341	MAJOR ESOPHAGEAL DISORDERS SOI 2	4,972	12,979	10,530	0.56711	81.13
342	MAJOR ESOPHAGEAL DISORDERS SOI 3	4,389	19,433	16,609	0.84912	85.47
343	OTHER ESOPHAGEAL DISORDERS SOI 1	13,851	8,949	6,716	0.39102	75.04
344	OTHER ESOPHAGEAL DISORDERS SOI 2	31,771	11,343	9,145	0.49562	80.63
345	OTHER ESOPHAGEAL DISORDERS SOI 3	11,584	18,052	17,945	0.78874	99.41
346	DIVERTICULITIS & DIVERTICULOSIS SOI 1	29,060	9,694	7,571	0.42359	78.10
347	DIVERTICULITIS & DIVERTICULOSIS SOI 2	69,468	12,553	10,391	0.54850	82.77

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
348	DIVERTICULITIS & DIVERTICULOSIS SOI 3	22,347	19,522	17,894	0.85299	91.66
349	INFLAMMATORY BOWEL DISEASE SOI 1	2,369	10,693	9,141	0.46723	85.48
350	INFLAMMATORY BOWEL DISEASE SOI 2	7,734	14,335	13,512	0.62635	94.26
351	INFLAMMATORY BOWEL DISEASE SOI 3	3,566	22,303	21,101	0.97452	94.61
352	GASTROINTESTINAL VASCULAR INSUFFICIENCY SOI 1	3,470	11,787	8,645	0.51502	73.34
353	GASTROINTESTINAL VASCULAR INSUFFICIENCY SOI 2	11,320	15,671	12,839	0.68471	81.93
354	GASTROINTESTINAL VASCULAR INSUFFICIENCY SOI 3	6,466	24,422	23,936	1.06708	98.01
355	INTESTINAL OBSTRUCTION SOI 1	22,156	8,521	7,379	0.37229	86.60
356	INTESTINAL OBSTRUCTION SOI 2	63,858	11,733	11,018	0.51266	93.90
357	INTESTINAL OBSTRUCTION SOI 3	27,519	19,030	19,724	0.83148	103.65
358	MAJOR GASTROINTESTINAL & PERITONEAL INFECTIONS SOI 1	2,288	10,437	8,745	0.45604	83.79
359	MAJOR GASTROINTESTINAL & PERITONEAL INFECTIONS SOI 2	21,934	14,541	14,315	0.63535	98.45
360	MAJOR GASTROINTESTINAL & PERITONEAL INFECTIONS SOI 3	20,031	23,209	24,279	1.01407	104.61
361	NON-BACTERIAL GASTROENTERITIS, NAUSEA & VOMITING SOI 1	15,481	7,256	6,229	0.31705	85.84
362	NON-BACTERIAL GASTROENTERITIS, NAUSEA & VOMITING SOI 2	77,412	8,780	8,125	0.38365	92.53
363	NON-BACTERIAL GASTROENTERITIS, NAUSEA & VOMITING SOI 3	27,764	13,247	14,074	0.57881	106.25
364	ABDOMINAL PAIN SOI 1	13,394	8,454	6,710	0.36938	79.38
365	ABDOMINAL PAIN SOI 2	31,846	10,831	9,033	0.47326	83.39
366	ABDOMINAL PAIN SOI 3	9,538	15,315	14,750	0.66918	96.31
367	MALFUNCTION, REACTION & COMPLICATION OF GI DEVICE OR PROCEDURE SOI 1	2,468	9,067	9,663	0.39619	106.57
368	MALFUNCTION, REACTION & COMPLICATION OF GI DEVICE OR PROCEDURE SOI 2	11,271	12,653	12,678	0.55284	100.20
369	MALFUNCTION, REACTION & COMPLICATION OF GI DEVICE OR PROCEDURE SOI 3	7,753	21,126	25,400	0.92307	120.23
370	OTHER & UNSPECIFIED GASTROINTESTINAL HEMORRHAGE SOI 1	15,328	9,011	7,725	0.39373	85.73
371	OTHER & UNSPECIFIED GASTROINTESTINAL HEMORRHAGE SOI 2	56,422	12,117	10,460	0.52943	86.33
372	OTHER & UNSPECIFIED GASTROINTESTINAL HEMORRHAGE SOI 3	34,096	18,447	18,185	0.80601	98.58
373	OTHER DIGESTIVE SYSTEM DIAGNOSES SOI 1	39,585	8,492	7,637	0.37105	89.93
374	OTHER DIGESTIVE SYSTEM DIAGNOSES SOI 2	49,911	12,033	11,254	0.52577	93.53
375	OTHER DIGESTIVE SYSTEM DIAGNOSES SOI 3	28,631	18,563	22,144	0.81107	119.29
376	MAJOR HEPATOBILIARY, PANCREAS & LIVER PROCEDURES SOI 4	2,439	123,750	127,822	5.40710	103.29
377	CHOLECYSTECTOMY & OTHER HEPATOBILRY, PANCREAS & ABDOMINAL PROCS SOI 4	6,124	83,345	76,941	3.64166	92.32
378	MAJOR PANCREAS, LIVER & SHUNT PROCEDURES SOI 1	1,055	23,228	23,547	1.01492	101.37
379	MAJOR PANCREAS, LIVER & SHUNT PROCEDURES SOI 2	3,740	32,886	26,341	1.43690	80.10
380	MAJOR PANCREAS, LIVER & SHUNT PROCEDURES SOI 3	4,353	59,975	49,514	2.62053	82.56
381	MAJOR BILIARY TRACT PROCEDURES SOI 1	331	21,992	14,746	0.96089	67.05
382	MAJOR BILIARY TRACT PROCEDURES SOI 2	2,501	33,821	25,399	1.47776	75.10
383	MAJOR BILIARY TRACT PROCEDURES SOI 3	1,759	52,733	42,618	2.30411	80.82
384	CHOLECYSTECTOMY EXCEPT LAPAROSCOPIC SOI 1	4,955	18,519	12,795	0.80916	69.09
385	CHOLECYSTECTOMY EXCEPT LAPAROSCOPIC SOI 2	10,870	27,907	21,823	1.21936	78.20
386	CHOLECYSTECTOMY EXCEPT LAPAROSCOPIC SOI 3	6,510	45,160	35,328	1.97321	78.23

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
387	LAPAROSCOPIC CHOLECYSTECTOMY SOI 1	22,420	15,304	9,739	0.66870	63.64
388	LAPAROSCOPIC CHOLECYSTECTOMY SOI 2	40,406	21,600	14,575	0.94379	67.48
389	LAPAROSCOPIC CHOLECYSTECTOMY SOI 3	21,521	34,117	28,254	1.49069	82.82
390	OTHER HEPATOBILIARY, PANCREAS & ABDOMINAL PROCEDURES SOI 1	976	21,608	16,982	0.94413	78.59
391	OTHER HEPATOBILIARY, PANCREAS & ABDOMINAL PROCEDURES SOI 2	1,164	27,626	25,090	1.20706	90.82
392	OTHER HEPATOBILIARY, PANCREAS & ABDOMINAL PROCEDURES SOI 3	1,999	48,893	46,045	2.13633	94.17
393	HEPATOBILIARY, PANCREAS & ABDOMINAL DIAGNOSES SOI 4	14,131	47,985	56,761	2.09665	118.29
394	HEPATIC COMA & OTHER MAJOR ACUTE LIVER DISORDERS SOI 1	1,445	7,827	6,654	0.34199	85.02
395	HEPATIC COMA & OTHER MAJOR ACUTE LIVER DISORDERS SOI 2	9,734	11,966	11,995	0.52282	100.24
396	HEPATIC COMA & OTHER MAJOR ACUTE LIVER DISORDERS SOI 3	9,411	21,459	25,083	0.93764	116.89
397	ALCOHOLIC LIVER DISEASE SOI 1	325	8,783	10,918	0.38375	124.31
398	ALCOHOLIC LIVER DISEASE SOI 2	3,949	12,043	10,570	0.52620	87.77
399	ALCOHOLIC LIVER DISEASE SOI 3	7,585	20,446	19,609	0.89335	95.91
400	MALIGNANCY OF HEPATOBILIARY SYSTEM & PANCREAS SOI 1	1,845	12,279	10,636	0.53650	86.62
401	MALIGNANCY OF HEPATOBILIARY SYSTEM & PANCREAS SOI 2	12,829	16,075	14,842	0.70236	92.33
402	MALIGNANCY OF HEPATOBILIARY SYSTEM & PANCREAS SOI 3	14,113	24,066	23,061	1.05154	95.82
403	DISORDERS OF PANCREAS EXCEPT MALIGNANCY SOI 1	15,573	10,771	9,420	0.47064	87.46
404	DISORDERS OF PANCREAS EXCEPT MALIGNANCY SOI 2	35,923	14,294	13,535	0.62454	94.69
405	DISORDERS OF PANCREAS EXCEPT MALIGNANCY SOI 3	17,138	23,516	27,121	1.02751	115.33
406	OTHER DISORDERS OF THE LIVER SOI 1	1,586	9,344	8,671	0.40827	92.80
407	OTHER DISORDERS OF THE LIVER SOI 2	9,635	12,620	11,347	0.55140	89.92
408	OTHER DISORDERS OF THE LIVER SOI 3	12,134	19,803	19,344	0.86526	97.68
409	DISORDERS OF GALLBLADDER & BILIARY TRACT SOI 1	7,602	10,312	8,396	0.45056	81.42
410	DISORDERS OF GALLBLADDER & BILIARY TRACT SOI 2	22,863	13,939	11,889	0.60904	85.30
411	DISORDERS OF GALLBLADDER & BILIARY TRACT SOI 3	12,539	20,912	19,784	0.91373	94.61
412	MUSCULOSKELETAL SYSTEM & CONN TISSUE PROCS EXCEPT SPINAL FUSION SOI 4	19,745	74,814	73,593	3.26892	98.37
413	SPINAL FUSION PROCEDURES SOI 4	1,412	129,524	101,473	5.65936	78.34
414	HIP JOINT REPLACEMENT SOI 1	103,793	28,571	14,995	1.24837	52.48
415	HIP JOINT REPLACEMENT SOI 2	81,313	33,508	18,726	1.46409	55.88
416	HIP JOINT REPLACEMENT SOI 3	24,970	41,192	26,691	1.79985	64.80
417	KNEE JOINT REPLACEMENT SOI 1	112,664	27,483	12,183	1.20082	44.33
418	KNEE JOINT REPLACEMENT SOI 2	127,114	30,571	15,465	1.33575	50.59
419	KNEE JOINT REPLACEMENT SOI 3	14,339	41,368	28,891	1.80752	69.84
420	DORSAL & LUMBAR FUSION PROC FOR CURVATURE OF BACK SOI 1	270	63,360	43,175	2.76843	68.14
421	DORSAL & LUMBAR FUSION PROC FOR CURVATURE OF BACK SOI 2	565	79,939	48,046	3.49285	60.10
422	DORSAL & LUMBAR FUSION PROC FOR CURVATURE OF BACK SOI 3	329	133,277	81,520	5.82336	61.17
423	DORSAL & LUMBAR FUSION PROC EXCEPT FOR CURVATURE OF BACK SOI 1	17,969	43,304	25,279	1.89211	58.37
424	DORSAL & LUMBAR FUSION PROC EXCEPT FOR CURVATURE OF BACK SOI 2	23,970	51,113	30,885	2.23332	60.43
425	DORSAL & LUMBAR FUSION PROC EXCEPT FOR CURVATURE OF BACK SOI 3	6,433	78,272	52,368	3.42000	66.91

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
426	AMPUTATION OF LOWER LIMB EXCEPT TOES SOI 1	2,329	16,331	12,845	0.71355	78.66
427	AMPUTATION OF LOWER LIMB EXCEPT TOES SOI 2	15,843	23,527	22,388	1.02799	95.16
428	AMPUTATION OF LOWER LIMB EXCEPT TOES SOI 3	18,078	40,154	42,244	1.75447	105.21
429	HIP & FEMUR PROCEDURES FOR TRAUMA EXCEPT JOINT REPLACEMENT SOI 1	22,748	18,892	10,141	0.82544	53.68
430	HIP & FEMUR PROCEDURES FOR TRAUMA EXCEPT JOINT REPLACEMENT SOI 2	77,347	23,039	13,343	1.00668	57.91
431	HIP & FEMUR PROCEDURES FOR TRAUMA EXCEPT JOINT REPLACEMENT SOI 3	38,443	32,405	23,162	1.41591	71.48
432	HIP & FEMUR PROCEDURES FOR NON-TRAUMA EXCEPT JOINT REPLACEMENT SOI 1	2,107	20,555	14,383	0.89814	69.97
433	HIP & FEMUR PROCEDURES FOR NON-TRAUMA EXCEPT JOINT REPLACEMENT SOI 2	7,092	27,220	19,476	1.18934	71.55
434	HIP & FEMUR PROCEDURES FOR NON-TRAUMA EXCEPT JOINT REPLACEMENT SOI 3	2,969	45,676	40,054	1.99574	87.69
435	INTERVERTEBRAL DISC EXCISION & DECOMPRESSION SOI 1	40,085	13,683	8,328	0.59784	60.87
436	INTERVERTEBRAL DISC EXCISION & DECOMPRESSION SOI 2	39,510	18,266	12,627	0.79811	69.13
437	INTERVERTEBRAL DISC EXCISION & DECOMPRESSION SOI 3	19,047	27,992	21,762	1.22309	77.74
438	SKIN GRAFT, EXCEPT HAND, FOR MUSCULOSKELETAL & CONN TISSUE DIXS SOI 1	403	18,568	16,295	0.81131	87.76
439	SKIN GRAFT, EXCEPT HAND, FOR MUSCULOSKELETAL & CONN TISSUE DXS SOI 2	946	34,592	39,008	1.51145	112.76
440	SKIN GRAFT, EXCEPT HAND, FOR MUSCULOSKELETAL & CONN TISSUE DXS SOI 3	563	74,090	74,115	3.23725	100.03
441	MUSCULOSKELETAL SYSTEM & CONN TISSUE PROCS EXC SPINAL FUSION SOI 4	94	161,588	114,658	7.06039	70.96
442	KNEE & LOWER LEG PROCEDURES EXCEPT FOOT SOI 1	19,958	15,523	10,525	0.67824	67.80
443	KNEE & LOWER LEG PROCEDURES EXCEPT FOOT SOI 2	24,427	22,481	16,709	0.98227	74.33
444	KNEE & LOWER LEG PROCEDURES EXCEPT FOOT SOI 3	6,382	39,594	36,875	1.73002	93.13
445	FOOT & TOE PROCEDURES SOI 1	3,124	13,374	9,662	0.58437	72.25
446	FOOT & TOE PROCEDURES SOI 2	11,700	19,005	17,747	0.83041	93.38
447	FOOT & TOE PROCEDURES SOI 3	10,760	28,497	27,439	1.24514	96.29
448	SHOULDER, UPPER ARM & FOREARM PROCEDURES SOI 1	20,666	13,379	8,294	0.58456	61.99
449	SHOULDER, UPPER ARM & FOREARM PROCEDURES SOI 2	38,530	22,449	13,913	0.98087	61.97
450	SHOULDER, UPPER ARM & FOREARM PROCEDURES SOI 3	4,598	35,320	28,966	1.54327	82.01
451	HAND & WRIST PROCEDURES SOI 1	2,081	11,438	8,453	0.49978	73.91
452	HAND & WRIST PROCEDURES SOI 2	2,533	17,067	17,234	0.74572	100.98
453	HAND & WRIST PROCEDURES SOI 3	580	33,436	35,627	1.46095	106.55
454	TENDON, MUSCLE & OTHER SOFT TISSUE PROCEDURES SOI 1	4,972	13,474	10,742	0.58873	79.73
455	TENDON, MUSCLE & OTHER SOFT TISSUE PROCEDURES SOI 2	5,998	20,447	18,679	0.89341	91.35
456	TENDON, MUSCLE & OTHER SOFT TISSUE PROCEDURES SOI 3	2,811	39,927	41,655	1.74456	104.33
457	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE PROCEDURES SOI 1	2,965	13,326	9,769	0.58227	73.30
458	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE PROCEDURES SOI 2	7,663	24,919	19,488	1.08882	78.21
459	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE PROCEDURES SOI 3	2,490	44,256	49,163	1.93369	111.09
460	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE PROCEDURES SOI 4	382	93,669	95,764	4.09275	102.24
461	CERV SPINAL FUSION & OTHER BACK/NECK PROC EXC DISC EXCIS/DECOMP SOI 1	20,447	25,096	15,984	1.09655	63.69
462	CERV SPINAL FUSION & OTHER BACK/NECK PROC EXC DISC EXCIS/DECOMP SOI 2	13,382	32,345	23,148	1.41325	71.57
463	CERV SPINAL FUSION & OTHER BACK/NECK PROC EXC DISC EXCIS/DECOMP SOI 3	2,623	56,133	42,887	2.45267	76.40
464	MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES SOI 4	8,379	49,282	59,374	2.15333	120.48

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
465	FRACTURE OF FEMUR SOI 1	3,381	6,673	6,026	0.29155	90.32
466	FRACTURE OF FEMUR SOI 2	10,009	9,376	9,401	0.40966	100.27
467	FRACTURE OF FEMUR SOI 3	5,045	15,003	15,984	0.65556	106.53
468	FRACTURE OF PELVIS OR DISLOCATION OF HIP SOI 1	5,588	7,360	5,716	0.32160	77.67
469	FRACTURE OF PELVIS OR DISLOCATION OF HIP SOI 2	14,811	9,655	8,050	0.42184	83.38
470	FRACTURE OF PELVIS OR DISLOCATION OF HIP SOI 3	7,817	14,101	13,489	0.61613	95.66
471	FRACTURES & DISLOCATIONS EXCEPT FEMUR, PELVIS & BACK SOI 1	9,175	6,977	5,872	0.30485	84.16
472	FRACTURES & DISLOCATIONS EXCEPT FEMUR, PELVIS & BACK SOI 2	23,612	9,766	8,633	0.42670	88.40
473	FRACTURES & DISLOCATIONS EXCEPT FEMUR, PELVIS & BACK SOI 3	7,762	15,318	15,668	0.66928	102.29
474	MUSCULOSKELETAL MALIGNANCY & PATHOL FRACTURE D/T MUSCSKEL MALIG SOI 1	1,214	12,015	10,773	0.52497	89.67
475	MUSCULOSKELETAL MALIGNANCY & PATHOL FRACTURE D/T MUSCSKEL MALIG SOI 2	7,295	15,636	13,777	0.68318	88.11
476	MUSCULOSKELETAL MALIGNANCY & PATHOL FRACTURE D/T MUSCSKEL MALIG SOI 3	8,635	26,030	26,362	1.13735	101.27
477	OSTEOMYELITIS, SEPTIC ARTHRITIS & OTHER MUSCULOSKELETAL INFECTIONS SOI 1	1,069	11,446	12,594	0.50014	110.03
478	OSTEOMYELITIS, SEPTIC ARTHRITIS & OTHER MUSCULOSKELETAL INFECTIONS SOI 2	9,188	16,914	16,056	0.73901	94.93
479	OSTEOMYELITIS, SEPTIC ARTHRITIS & OTHER MUSCULOSKELETAL INFECTIONS SOI 3	7,284	26,743	28,155	1.16849	105.28
480	CONNECTIVE TISSUE DISORDERS SOI 1	4,287	10,681	10,869	0.46670	101.76
481	CONNECTIVE TISSUE DISORDERS SOI 2	6,892	14,698	14,819	0.64223	100.82
482	CONNECTIVE TISSUE DISORDERS SOI 3	4,767	24,502	28,523	1.07059	116.41
483	OTHER BACK & NECK DISORDERS, FRACTURES & INJURIES SOI 1	45,411	9,109	7,578	0.39801	83.19
484	OTHER BACK & NECK DISORDERS, FRACTURES & INJURIES SOI 2	57,805	12,194	10,806	0.53281	88.62
485	OTHER BACK & NECK DISORDERS, FRACTURES & INJURIES SOI 3	20,057	18,779	18,405	0.82051	98.01
486	MALFUNCTION, REACTION, COMPLIC OF ORTHOPEDIC DEVICE OR PROCEDURE SOI 1	4,705	7,440	5,823	0.32508	78.26
487	MALFUNCTION, REACTION, COMPLIC OF ORTHOPEDIC DEVICE OR PROCEDURE SOI 2	8,776	11,756	12,586	0.51368	107.06
488	MALFUNCTION, REACTION, COMPLIC OF ORTHOPEDIC DEVICE OR PROCEDURE SOI 3	3,578	21,171	23,927	0.92504	113.02
489	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES SOI 1	15,930	7,296	6,758	0.31877	92.63
490	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES SOI 2	40,607	9,911	9,080	0.43304	91.62
491	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES SOI 3	13,217	15,923	17,927	0.69574	112.58
492	SKIN, SUBCUTANEOUS TISSUE, BREAST & RELATED PROCEDURES SOI 4	928	94,230	98,601	4.11727	104.64
493	SKIN GRAFT FOR SKIN & SUBCUTANEOUS TISSUE DIAGNOSES SOI 1	4,876	17,871	18,293	0.78085	102.36
494	SKIN GRAFT FOR SKIN & SUBCUTANEOUS TISSUE DIAGNOSES SOI 2	4,573	27,245	30,026	1.19043	110.21
495	SKIN GRAFT FOR SKIN & SUBCUTANEOUS TISSUE DIAGNOSES SOI 3	2,168	51,500	57,364	2.25023	111.39
496	MASTECTOMY PROCEDURES SOI 1	18,817	11,442	7,037	0.49995	61.50
497	MASTECTOMY PROCEDURES SOI 2	8,707	14,138	11,707	0.61776	82.80
498	MASTECTOMY PROCEDURES SOI 3	603	27,577	25,560	1.20494	92.68
499	BREAST PROCEDURES EXCEPT MASTECTOMY SOI 1	4,547	12,861	9,809	0.56193	76.27
500	BREAST PROCEDURES EXCEPT MASTECTOMY SOI 2	363	18,622	12,953	0.81366	69.56
501	BREAST PROCEDURES EXCEPT MASTECTOMY SOI 3	344	29,462	25,566	1.28732	86.77
502	OTHER SKIN, SUBCUTANEOUS TISSUE & RELATED PROCEDURES SOI 1	3,234	13,486	10,971	0.58925	81.36
503	OTHER SKIN, SUBCUTANEOUS TISSUE & RELATED PROCEDURES SOI 2	6,677	21,955	20,810	0.95928	94.78

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
504	OTHER SKIN, SUBCUTANEOUS TISSUE & RELATED PROCEDURES SOI 3	3,578	41,500	42,669	1.81328	102.82
505	SKIN, SUBCUTANEOUS TISSUE & BREAST DIAGNOSES SOI 4	4,973	47,526	64,234	2.07659	135.15
506	SKIN ULCERS SOI 1	3,647	9,903	10,730	0.43270	108.35
507	SKIN ULCERS SOI 2	19,597	13,483	14,482	0.58911	107.41
508	SKIN ULCERS SOI 3	14,080	21,285	24,761	0.93003	116.33
509	MAJOR SKIN DISORDERS SOI 1	1,057	8,476	7,539	0.37035	88.94
510	MAJOR SKIN DISORDERS SOI 2	4,325	11,485	11,319	0.50182	98.55
511	MAJOR SKIN DISORDERS SOI 3	1,907	20,440	26,261	0.89308	128.48
512	MALIGNANT BREAST DISORDERS SOI 1	195	8,023	7,262	0.35057	90.51
513	MALIGNANT BREAST DISORDERS SOI 2	1,055	12,263	10,417	0.53581	84.95
514	MALIGNANT BREAST DISORDERS SOI 3	1,153	22,880	22,574	0.99971	98.66
515	CELLULITIS & OTHER BACTERIAL SKIN INFECTIONS SOI 1	28,242	8,437	7,881	0.36864	93.41
516	CELLULITIS & OTHER BACTERIAL SKIN INFECTIONS SOI 2	84,615	11,377	11,071	0.49708	97.31
517	CELLULITIS & OTHER BACTERIAL SKIN INFECTIONS SOI 3	38,912	17,322	18,230	0.75684	105.24
518	CONTUSION, OPEN WOUND & OTHER TRAUMA TO SKIN & SUBCUT TISSUE SOI 1	5,758	7,515	6,691	0.32836	89.04
519	CONTUSION, OPEN WOUND & OTHER TRAUMA TO SKIN & SUBCUT TISSUE SOI 2	17,449	9,880	8,678	0.43169	87.84
520	CONTUSION, OPEN WOUND & OTHER TRAUMA TO SKIN & SUBCUT TISSUE SOI 3	5,491	15,203	16,259	0.66429	106.95
521	OTHER SKIN, SUBCUTANEOUS TISSUE & BREAST DISORDERS SOI 1	2,888	7,296	7,067	0.31879	96.86
522	OTHER SKIN, SUBCUTANEOUS TISSUE & BREAST DISORDERS SOI 2	5,504	10,230	10,282	0.44699	100.51
523	OTHER SKIN, SUBCUTANEOUS TISSUE & BREAST DISORDERS SOI 3	2,067	17,037	19,481	0.74440	114.34
524	PROCEDURES FOR ENDOCRINE, NUTRITIONAL & METABOLIC DISORDERS SOI 4	877	111,134	123,931	4.85585	111.52
525	PITUITARY & ADRENAL PROCEDURES SOI 1	1,480	22,134	14,567	0.96711	65.81
526	PITUITARY & ADRENAL PROCEDURES SOI 2	758	28,687	18,736	1.25343	65.31
527	PITUITARY & ADRENAL PROCEDURES SOI 3	360	50,271	40,993	2.19653	81.54
528	PROCEDURES FOR OBESITY SOI 1	2,825	25,834	14,313	1.12877	55.41
529	PROCEDURES FOR OBESITY SOI 2	5,619	29,329	20,027	1.28151	68.28
530	PROCEDURES FOR OBESITY SOI 3	1,123	46,351	42,658	2.02524	92.03
531	THYROID, PARATHYROID & THYROGLOSSAL PROCEDURES SOI 1	11,038	11,423	7,188	0.49912	62.93
532	THYROID, PARATHYROID & THYROGLOSSAL PROCEDURES SOI 2	5,750	15,913	14,451	0.69532	90.81
533	THYROID, PARATHYROID & THYROGLOSSAL PROCEDURES SOI 3	762	40,397	42,564	1.76508	105.37
534	OTHER PROCS FOR ENDOCRINE, NUTRITIONAL & METABOLIC DISORDERS SOI 1	679	20,998	17,044	0.91750	81.17
535	OTHER PROCS FOR ENDOCRINE, NUTRITIONAL & METABOLIC DISORDERS SOI 2	1,517	28,724	26,794	1.25508	93.28
536	OTHER PROCS FOR ENDOCRINE, NUTRITIONAL & METABOLIC DISORDERS SOI 3	1,798	47,289	43,383	2.06623	91.74
537	ENDOCRINE DIAGNOSES SOI 4	12,843	37,806	45,564	1.65187	120.52
538	DIABETES SOI 1	25,850	7,522	7,292	0.32867	96.94
539	DIABETES SOI 2	38,067	9,923	9,977	0.43359	100.54
540	DIABETES SOI 3	25,668	15,130	16,051	0.66110	106.08
541	MALNUTRITION, FAILURE TO THRIVE & OTHER NUTRITIONAL DISORDERS SOI 1	411	8,997	7,735	0.39311	85.97
542	MALNUTRITION, FAILURE TO THRIVE & OTHER NUTRITIONAL DISORDERS SOI 2	7,185	10,257	9,848	0.44817	96.02

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
543	MALNUTRITION, FAILURE TO THRIVE & OTHER NUTRITIONAL DISORDERS SOI 3	8,164	17,102	19,155	0.74724	112.00
544	HYPOVOLEMIA & RELATED ELECTROLYTE DISORDERS SOI 1	6,590	7,052	6,911	0.30812	98.00
545	HYPOVOLEMIA & RELATED ELECTROLYTE DISORDERS SOI 2	89,500	9,721	9,473	0.42473	97.45
546	HYPOVOLEMIA & RELATED ELECTROLYTE DISORDERS SOI 3	54,483	14,449	15,440	0.63132	106.86
547	INBORN ERRORS OF METABOLISM SOI 1	149	7,736	6,833	0.33802	88.32
548	INBORN ERRORS OF METABOLISM SOI 2	702	13,269	18,115	0.57978	136.52
549	INBORN ERRORS OF METABOLISM SOI 3	586	20,156	22,286	0.88068	110.57
550	OTHER ENDOCRINE DISORDERS SOI 1	6,047	8,944	8,257	0.39081	92.32
551	OTHER ENDOCRINE DISORDERS SOI 2	12,184	13,490	12,734	0.58943	94.39
552	OTHER ENDOCRINE DISORDERS SOI 3	8,386	19,837	19,164	0.86673	96.61
553	ELECTROLYTE DISORDERS EXCEPT HYPOVOLEMIA RELATED SOI 1	10,635	7,273	6,296	0.31778	86.57
554	ELECTROLYTE DISORDERS EXCEPT HYPOVOLEMIA RELATED SOI 2	49,001	9,964	10,008	0.43535	100.45
555	ELECTROLYTE DISORDERS EXCEPT HYPOVOLEMIA RELATED SOI 3	26,003	15,070	15,107	0.65848	100.25
556	URINARY TRACT & RELATED PROCEDURES EXCEPT KIDNEY TRANSPLANT SOI 4	6,007	90,949	92,207	3.97391	101.38
557	KIDNEY TRANSPLANT SOI 1	1,779	68,417	26,450	2.98939	38.66
558	KIDNEY TRANSPLANT SOI 2	4,435	74,891	33,307	3.27225	44.47
559	KIDNEY TRANSPLANT SOI 3	2,986	95,252	54,104	4.16191	56.80
560	KIDNEY TRANSPLANT SOI 4	469	152,275	108,369	6.65346	71.17
561	MAJOR BLADDER PROCEDURES SOI 1	261	23,558	17,038	1.02935	72.32
562	MAJOR BLADDER PROCEDURES SOI 2	2,322	33,369	25,393	1.45802	76.10
563	MAJOR BLADDER PROCEDURES SOI 3	3,430	51,743	36,167	2.26083	69.90
564	KIDNEY & URINARY TRACT PROCEDURES FOR MALIGNANCY SOI 1	5,198	21,061	12,923	0.92024	61.36
565	KIDNEY & URINARY TRACT PROCEDURES FOR MALIGNANCY SOI 2	7,249	25,662	16,673	1.12126	64.97
566	KIDNEY & URINARY TRACT PROCEDURES FOR MALIGNANCY SOI 3	3,807	42,637	31,878	1.86295	74.77
567	KIDNEY & URINARY TRACT PROCEDURES FOR NONMALIGNANCY SOI 1	4,454	18,869	12,480	0.82447	66.14
568	KIDNEY & URINARY TRACT PROCEDURES FOR NONMALIGNANCY SOI 2	6,793	23,569	18,856	1.02982	80.00
569	KIDNEY & URINARY TRACT PROCEDURES FOR NONMALIGNANCY SOI 3	5,559	42,101	40,957	1.83953	97.28
570	RENAL DIALYSIS ACCESS DEVICE PROCEDURE ONLY SOI 1	5,076	15,328	11,744	0.66974	76.62
571	RENAL DIALYSIS ACCESS DEVICE PROCEDURE ONLY SOI 2	13,693	21,856	18,499	0.95498	84.64
572	RENAL DIALYSIS ACCESS DEVICE PROCEDURE ONLY SOI 3	7,291	42,455	39,841	1.85503	93.84
573	OTHER BLADDER PROCEDURES SOI 1	4,345	12,220	9,427	0.53393	77.15
574	OTHER BLADDER PROCEDURES SOI 2	3,289	19,783	14,467	0.86438	73.13
575	OTHER BLADDER PROCEDURES SOI 3	1,087	34,616	56,740	1.51251	163.91
576	URETHRAL & TRANSURETHRAL PROCEDURES SOI 1	10,757	10,171	6,864	0.44441	67.49
577	URETHRAL & TRANSURETHRAL PROCEDURES SOI 2	18,639	15,320	12,477	0.66937	81.44
578	URETHRAL & TRANSURETHRAL PROCEDURES SOI 3	4,706	30,204	31,939	1.31973	105.74
579	OTHER KIDNEY, URINARY TRACT & RELATED PROCEDURES SOI 1	8,349	19,668	13,309	0.85937	67.67
580	OTHER KIDNEY, URINARY TRACT & RELATED PROCEDURES SOI 2	15,565	23,663	19,777	1.03393	83.58
581	OTHER KIDNEY, URINARY TRACT & RELATED PROCEDURES SOI 3	8,254	42,583	44,844	1.86061	105.31

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
582	KIDNEY & URINARY TRACT DIAGNOSES SOI 4	30,700	43,100	51,509	1.88320	119.51
583	RENAL FAILURE SOI 1	3,835	9,930	12,839	0.43387	129.30
584	RENAL FAILURE SOI 2	21,366	13,023	13,455	0.56902	103.32
585	RENAL FAILURE SOI 3	136,617	18,960	20,475	0.82844	107.99
586	KIDNEY & URINARY TRACT MALIGNANCY SOI 1	424	10,142	14,535	0.44313	143.32
587	KIDNEY & URINARY TRACT MALIGNANCY SOI 2	2,681	13,072	12,008	0.57117	91.86
588	KIDNEY & URINARY TRACT MALIGNANCY SOI 3	2,596	21,263	20,221	0.92908	95.10
589	NEPHRITIS & NEPHROSIS SOI 1	146	7,859	7,061	0.34337	89.86
590	NEPHRITIS & NEPHROSIS SOI 2	636	11,850	10,770	0.51776	90.89
591	NEPHRITIS & NEPHROSIS SOI 3	842	22,403	26,607	0.97886	118.77
592	KIDNEY & URINARY TRACT INFECTIONS SOI 1	17,271	7,865	6,485	0.34363	82.45
593	KIDNEY & URINARY TRACT INFECTIONS SOI 2	134,546	10,528	9,225	0.46000	87.63
594	KIDNEY & URINARY TRACT INFECTIONS SOI 3	88,350	15,894	15,657	0.69447	98.51
595	URINARY STONES & ACQUIRED UPPER URINARY TRACT OBSTRUCTION SOI 1	5,264	8,313	6,630	0.36321	79.76
596	URINARY STONES & ACQUIRED UPPER URINARY TRACT OBSTRUCTION SOI 2	16,382	10,962	8,851	0.47898	80.74
597	URINARY STONES & ACQUIRED UPPER URINARY TRACT OBSTRUCTION SOI 3	3,815	18,226	16,279	0.79635	89.32
598	MALFUNCTION, REACTION, COMPLIC OF GENITOURINARY DEVICE OR PROC SOI 1	932	6,942	6,191	0.30331	89.18
599	MALFUNCTION, REACTION, COMPLIC OF GENITOURINARY DEVICE OR PROC SOI 2	17,322	11,590	11,208	0.50642	96.70
600	MALFUNCTION, REACTION, COMPLIC OF GENITOURINARY DEVICE OR PROC SOI 3	33,102	19,704	21,441	0.86094	108.82
601	OTHER KIDNEY & URINARY TRACT DIAGNOSES, SIGNS & SYMPTOMS SOI 1	15,527	8,630	8,327	0.37708	96.49
602	OTHER KIDNEY & URINARY TRACT DIAGNOSES, SIGNS & SYMPTOMS SOI 2	21,246	12,271	12,250	0.53618	99.83
603	OTHER KIDNEY & URINARY TRACT DIAGNOSES, SIGNS & SYMPTOMS SOI 3	14,452	18,784	19,672	0.82076	104.73
604	MALE REPRODUCTIVE SYSTEM & RELATED PROCEDURES SOI 4	641	71,004	84,975	3.10241	119.68
605	MAJOR MALE PELVIC PROCEDURES SOI 1	14,617	17,729	10,147	0.77465	57.23
606	MAJOR MALE PELVIC PROCEDURES SOI 2	5,992	20,939	14,107	0.91492	67.37
607	MAJOR MALE PELVIC PROCEDURES SOI 3	605	33,226	25,241	1.45178	75.97
608	PENIS PROCEDURES SOI 1	1,324	11,764	9,123	0.51403	77.55
609	PENIS PROCEDURES SOI 2	2,590	21,123	12,752	0.92296	60.37
610	PENIS PROCEDURES SOI 3	274	38,253	43,456	1.67142	113.60
611	TRANSURETHRAL PROSTATECTOMY SOI 1	31,562	9,247	5,380	0.40402	58.19
612	TRANSURETHRAL PROSTATECTOMY SOI 2	22,430	12,001	9,197	0.52436	76.64
613	TRANSURETHRAL PROSTATECTOMY SOI 3	3,078	24,819	23,138	1.08443	93.23
614	TESTES & SCROTAL PROCEDURES SOI 1	558	11,613	10,941	0.50743	94.21
615	TESTES & SCROTAL PROCEDURES SOI 2	540	19,875	18,639	0.86841	93.78
616	TESTES & SCROTAL PROCEDURES SOI 3	242	34,134	32,117	1.49145	94.09
617	OTHER MALE REPRODUCTIVE SYSTEM & RELATED PROCEDURES SOI 1	718	10,201	7,083	0.44570	69.44
618	OTHER MALE REPRODUCTIVE SYSTEM & RELATED PROCEDURES SOI 2	2,392	16,905	11,803	0.73864	69.82
619	OTHER MALE REPRODUCTIVE SYSTEM & RELATED PROCEDURES SOI 3	1,359	23,420	22,576	1.02331	96.40
620	MALE REPRODUCTIVE SYSTEM DIAGNOSES SOI 4	494	34,322	40,510	1.49966	118.03

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
621	MALIGNANCY, MALE REPRODUCTIVE SYSTEM SOI 1	323	8,939	9,904	0.39060	110.79
622	MALIGNANCY, MALE REPRODUCTIVE SYSTEM SOI 2	2,041	12,177	12,138	0.53207	99.68
623	MALIGNANCY, MALE REPRODUCTIVE SYSTEM SOI 3	1,633	20,035	20,891	0.87541	104.27
624	MALE REPRODUCTIVE SYSTEM DIAGNOSES EXCEPT MALIGNANCY SOI 1	2,337	7,283	6,250	0.31820	85.81
625	MALE REPRODUCTIVE SYSTEM DIAGNOSES EXCEPT MALIGNANCY SOI 2	7,273	10,115	9,650	0.44197	95.40
626	MALE REPRODUCTIVE SYSTEM DIAGNOSES EXCEPT MALIGNANCY SOI 3	3,061	15,808	16,218	0.69072	102.59
627	FEMALE REPRODUCTIVE SYSTEM & RELATED PROCEDURES SOI 4	1,189	85,512	93,504	3.73635	109.35
628	PELVIC EVISCERATION, RADICAL HYSTERECTOMY & OTH RADICAL GYN PROCS SOI 1	949	17,376	11,926	0.75920	68.63
629	PELVIC EVISCERATION, RADICAL HYSTERECTOMY & OTH RADICAL GYN PROCS SOI 2	1,197	23,505	19,978	1.02700	85.00
630	PELVIC EVISCERATION, RADICAL HYSTERECTOMY & OTH RADICAL GYN PROCS SOI 3	415	51,428	56,696	2.24708	110.24
631	UTERINE & ADNEXA PROCEDURES FOR OVARIAN & ADNEXAL MALIGNANCY SOI 1	624	18,490	11,579	0.80790	62.62
632	UTERINE & ADNEXA PROCEDURES FOR OVARIAN & ADNEXAL MALIGNANCY SOI 2	2,601	27,025	20,798	1.18084	76.96
633	UTERINE & ADNEXA PROCEDURES FOR OVARIAN & ADNEXAL MALIGNANCY SOI 3	1,561	47,825	43,048	2.08963	90.01
634	UTERINE & ADNEXA PROCEDURES FOR NON-OVARIAN & NON-ADNEXAL MALIG SOI 1	4,187	14,553	9,059	0.63589	62.25
635	UTERINE & ADNEXA PROCEDURES FOR NON-OVARIAN & NON-ADNEXAL MALIG SOI 2	5,848	18,942	14,827	0.82765	78.27
636	UTERINE & ADNEXA PROCEDURES FOR NON-OVARIAN & NON-ADNEXAL MALIG SOI 3	1,293	37,166	34,905	1.62393	93.92
637	UTERINE & ADNEXA PROCEDURES FOR NON-MALIGNANCY EXCEPT LEIOMYOMA SOI 1	24,610	12,479	7,235	0.54525	57.97
638	UTERINE & ADNEXA PROCEDURES FOR NON-MALIGNANCY EXCEPT LEIOMYOMA SOI 2	16,461	15,372	10,382	0.67168	67.54
639	UTERINE & ADNEXA PROCEDURES FOR NON-MALIGNANCY EXCEPT LEIOMYOMA SOI 3	1,993	29,319	28,109	1.28105	95.87
640	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES SOI 1	21,359	10,655	6,154	0.46555	57.76
641	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES SOI 2	13,384	13,421	8,174	0.58642	60.91
642	FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES SOI 3	726	22,065	16,683	0.96411	75.61
643	DILATION & CURETTAGE FOR NON-OBSTETRIC DIAGNOSES SOI 1	514	10,526	8,928	0.45993	84.81
644	DILATION & CURETTAGE FOR NON-OBSTETRIC DIAGNOSES SOI 2	898	15,228	12,897	0.66536	84.69
645	DILATION & CURETTAGE FOR NON-OBSTETRIC DIAGNOSES SOI 3	353	22,494	19,826	0.98286	88.14
646	OTHER FEMALE REPRODUCTIVE SYSTEM & RELATED PROCEDURES SOI 1	2,540	11,359	8,469	0.49631	74.56
647	OTHER FEMALE REPRODUCTIVE SYSTEM & RELATED PROCEDURES SOI 2	1,500	18,000	19,069	0.78650	105.94
648	OTHER FEMALE REPRODUCTIVE SYSTEM & RELATED PROCEDURES SOI 3	534	42,618	46,704	1.86213	109.59
649	UTERINE & ADNEXA PROCEDURES FOR LEIOMYOMA SOI 1	3,992	12,203	7,293	0.53318	59.77
650	UTERINE & ADNEXA PROCEDURES FOR LEIOMYOMA SOI 2	2,529	15,176	10,575	0.66307	69.69
651	UTERINE & ADNEXA PROCEDURES FOR LEIOMYOMA SOI 3	265	31,326	29,741	1.36876	94.94
652	FEMALE REPRODUCTIVE SYSTEM DIAGNOSES SOI 4	738	44,087	52,567	1.92633	119.23
653	FEMALE REPRODUCTIVE SYSTEM MALIGNANCY SOI 1	484	8,288	7,096	0.36213	85.62
654	FEMALE REPRODUCTIVE SYSTEM MALIGNANCY SOI 2	2,237	12,702	12,472	0.55502	98.19
655	FEMALE REPRODUCTIVE SYSTEM MALIGNANCY SOI 3	2,739	22,258	23,768	0.97252	106.79
656	FEMALE REPRODUCTIVE SYSTEM INFECTIONS SOI 1	430	9,475	8,278	0.41400	87.36
657	FEMALE REPRODUCTIVE SYSTEM INFECTIONS SOI 2	1,749	14,145	14,257	0.61805	100.79
658	FEMALE REPRODUCTIVE SYSTEM INFECTIONS SOI 3	1,611	21,685	21,501	0.94748	99.15
659	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS SOI 1	1,480	7,763	7,889	0.33921	101.62

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
660	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS SOI 2	2,061	9,643	9,278	0.42134	96.21
661	MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS SOI 3	645	14,702	14,322	0.64237	97.42
662	O.R. PROC FOR OBSTETRIC DIAGNOSES EXCEPT CESAREAN DELIVERY SOI 4	13	77,830	107,025	3.40067	137.51
663	CESAREAN DELIVERY SOI 1	2,251	9,036	5,335	0.39481	59.04
664	CESAREAN DELIVERY SOI 2	1,347	12,054	11,250	0.52669	93.33
665	CESAREAN DELIVERY SOI 3	499	18,805	19,578	0.82166	104.11
666	CESAREAN DELIVERY SOI 4	44	47,871	45,704	2.09167	95.47
667	VAGINAL DELIVERY PROCEDURES SOI 1	106	7,211	3,934	0.31508	54.56
668	VAGINAL DELIVERY PROCEDURES SOI 2	107	8,299	8,541	0.36261	102.92
669	VAGINAL DELIVERY PROCEDURES SOI 3	37	16,442	13,225	0.71841	80.43
670	OTHER PROCS FOR OBSTETRIC DIAGNOSES EXCEPT DELIVERY DIAGNOSES SOI 1	183	9,183	6,535	0.40123	71.16
671	OTHER PROCS FOR OBSTETRIC DIAGNOSES EXCEPT DELIVERY DIAGNOSES SOI 2	239	10,160	6,269	0.44391	61.70
672	OTHER PROCS FOR OBSTETRIC DIAGNOSES EXCEPT DELIVERY DIAGNOSES SOI 3	59	17,103	15,828	0.74728	92.55
673	ANTEPARTUM DIAGNOSES EXCEPT VAGINAL DELIVERY DIAGNOSIS SOI 4	18	34,514	28,605	1.50806	82.88
674	VAGINAL DELIVERY SOI 1	2,989	5,293	3,209	0.23129	60.62
675	VAGINAL DELIVERY SOI 2	2,376	5,886	4,034	0.25717	68.53
676	VAGINAL DELIVERY SOI 3	604	9,441	11,215	0.41249	118.80
677	VAGINAL DELIVERY SOI 4	18	29,705	29,042	1.29791	97.77
678	POSTPARTUM & ABORTION DIAGNOSES W/O PROCEDURE SOI 1	125	4,275	3,319	0.18680	77.64
679	POSTPARTUM & ABORTION DIAGNOSES W/O PROCEDURE SOI 2	235	6,432	6,053	0.28104	94.11
680	POSTPARTUM & ABORTION DIAGNOSES W/O PROCEDURE SOI 3	128	12,803	12,836	0.55940	100.26
681	ANTEPARTUM DIAGNOSES SOI 1	689	4,550	4,405	0.19881	96.80
682	ANTEPARTUM DIAGNOSES SOI 2	1,538	6,422	7,485	0.28060	116.55
683	ANTEPARTUM DIAGNOSES SOI 3	809	9,715	11,534	0.42450	118.72
692	FULL TERM NEONATE WITH MAJOR PROBLEMS SOI 1 & 2	4	13,899	12,136	0.60731	87.31
693	FULL TERM NEONATE WITH MAJOR PROBLEMS SOI 3 & 4	9	45,006	56,602	1.96650	125.76
698	PROCEDURES OF BLOOD & BLOOD-FORMING ORGANS SOI 4	376	105,697	91,141	4.61831	86.23
699	SPLENECTOMY SOI 1	444	23,547	16,441	1.02888	69.82
700	SPLENECTOMY SOI 2	948	34,249	30,597	1.49646	89.34
701	SPLENECTOMY SOI 3	586	60,033	53,513	2.62308	89.14
702	OTHER PROCEDURES OF BLOOD & BLOOD-FORMING ORGANS SOI 1	952	15,020	12,542	0.65629	83.50
703	OTHER PROCEDURES OF BLOOD & BLOOD-FORMING ORGANS SOI 2	597	23,031	23,012	1.00630	99.92
704	OTHER PROCEDURES OF BLOOD & BLOOD-FORMING ORGANS SOI 3	259	46,591	41,811	2.03575	89.74
705	ANEMIA & DIAGNOSES OF BLOOD & BLOOD-FORMING ORGANS SOI 4	4,630	51,720	72,410	2.25983	140.00
706	MAJOR HEMATOLOGIC/IMMUNOLOGIC DIAG EXC SICKLE CELL CRISIS & COAGUL SOI 1	2,509	11,468	12,633	0.50109	110.15
707	MAJOR HEMATOLOGIC/IMMUNOLOGIC DIAG EXC SICKLE CELL CRISIS & COAGUL SOI 2	14,450	15,166	15,331	0.66265	101.09
708	MAJOR HEMATOLOGIC/IMMUNOLOGIC DIAG EXC SICKLE CELL CRISIS & COAGUL SOI 3	8,767	25,833	31,255	1.12873	120.99
709	COAGULATION & PLATELET DISORDERS SOI 1	6,790	12,546	26,268	0.54817	209.38
710	COAGULATION & PLATELET DISORDERS SOI 2	7,239	19,435	32,282	0.84920	166.10

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
711	COAGULATION & PLATELET DISORDERS SOI 3	3,060	39,788	101,651	1.73850	255.48
712	SICKLE CELL ANEMIA CRISIS SOI 1	6,135	10,917	10,949	0.47702	100.29
713	SICKLE CELL ANEMIA CRISIS SOI 2	5,431	14,837	14,801	0.64827	99.76
714	SICKLE CELL ANEMIA CRISIS SOI 3	1,757	23,068	23,395	1.00791	101.42
715	OTHER ANEMIA & DISORDERS OF BLOOD & BLOOD-FORMING ORGANS SOI 1	33,188	8,715	8,519	0.38080	97.74
716	OTHER ANEMIA & DISORDERS OF BLOOD & BLOOD-FORMING ORGANS SOI 2	41,571	11,427	10,908	0.49930	95.46
717	OTHER ANEMIA & DISORDERS OF BLOOD & BLOOD-FORMING ORGANS SOI 3	17,863	16,473	18,604	0.71978	112.93
718	PROCEDURES FOR LYMPHATIC/HEMATOPOIETIC/OTHER NEOPLASMS SOI 4	1,689	119,309	132,728	5.21304	111.25
719	MAJOR O.R. PROCS FOR LYMPHATIC/HEMATOPOIETIC/OTHER NEOPLASMS SOI 1	1,010	23,033	20,000	1.00641	86.83
720	MAJOR O.R. PROCS FOR LYMPHATIC/HEMATOPOIETIC/OTHER NEOPLASMS SOI 2	2,873	34,250	27,721	1.49651	80.94
721	MAJOR O.R. PROCS FOR LYMPHATIC/HEMATOPOIETIC/OTHER NEOPLASMS SOI 3	1,917	62,988	54,245	2.75217	86.12
722	OTHER O.R. PROCS FOR LYMPHATIC/HEMATOPOIETIC/OTHER NEOPLASMS SOI 1	2,776	15,427	12,654	0.67404	82.03
723	OTHER O.R. PROCS FOR LYMPHATIC/HEMATOPOIETIC/OTHER NEOPLASMS SOI 2	4,469	23,966	25,118	1.04718	104.81
724	OTHER O.R. PROCS FOR LYMPHATIC/HEMATOPOIETIC/OTHER NEOPLASMS SOI 3	2,402	49,127	53,076	2.14656	108.04
725	LEUKEMIA, LYMPHOMA, MYELOMA, CHEMOTHERAPY, AND RADIOTHERAPY SOI 4	6,317	83,294	89,608	3.63941	107.58
726	ACUTE LEUKEMIA SOI 1	618	15,411	20,094	0.67336	130.39
727	ACUTE LEUKEMIA SOI 2	2,671	24,598	38,214	1.07477	155.36
728	ACUTE LEUKEMIA SOI 3	3,364	50,470	59,859	2.20523	118.60
729	LYMPHOMA, MYELOMA & NON-ACUTE LEUKEMIA SOI 1	2,310	14,625	14,066	0.63904	96.17
730	LYMPHOMA, MYELOMA & NON-ACUTE LEUKEMIA SOI 2	10,157	20,231	19,460	0.88396	96.19
731	LYMPHOMA, MYELOMA & NON-ACUTE LEUKEMIA SOI 3	10,249	32,223	33,592	1.40796	104.25
732	RADIOTHERAPY SOI 1	683	13,313	11,101	0.58168	83.39
733	RADIOTHERAPY SOI 2	1,887	25,220	17,640	1.10197	69.94
734	RADIOTHERAPY SOI 3	328	37,702	36,146	1.64734	95.87
735	CHEMOTHERAPY SOI 1	4,689	12,739	10,443	0.55663	81.98
736	CHEMOTHERAPY SOI 2	21,073	16,543	13,824	0.72280	83.57
737	CHEMOTHERAPY SOI 3	4,969	39,361	45,099	1.71985	114.58
738	LYMPHATIC & OTHER MALIGNANCIES & NEOPLASMS OF UNCERTAIN BEHAVIOR SOI 1	1,174	9,853	10,545	0.43053	107.02
739	LYMPHATIC & OTHER MALIGNANCIES & NEOPLASMS OF UNCERTAIN BEHAVIOR SOI 2	6,955	14,880	17,226	0.65018	115.77
740	LYMPHATIC & OTHER MALIGNANCIES & NEOPLASMS OF UNCERTAIN BEHAVIOR SOI 3	7,335	24,155	27,025	1.05542	111.88
741	LYMPHATIC & OTHER MALIGNANCIES & NEOPLASMS OF UNCERTAIN BEHAVIOR SOI 4	1,382	47,632	65,403	2.08122	137.31
742	INFECTIOUS & PARASITIC DISEASES W O.R. PROCEDURE SOI 4	10,444	111,980	110,598	4.89283	98.77
743	INFECTIOUS & PARASITIC DISEASES INCLUDING HIV W O.R. PROCEDURE SOI 1	306	25,111	26,472	1.09718	105.42
744	INFECTIOUS & PARASITIC DISEASES INCLUDING HIV W O.R. PROCEDURE SOI 2	3,304	38,299	34,580	1.67344	90.29
745	INFECTIOUS & PARASITIC DISEASES INCLUDING HIV W O.R. PROCEDURE SOI 3	9,137	61,574	62,713	2.69041	101.85
746	POST-OP, POST-TRAUMA, OTHER DEVICE INFECTIONS W O.R. PROCEDURE SOI 1	2,778	19,896	17,934	0.86932	90.14
747	POST-OP, POST-TRAUMA, OTHER DEVICE INFECTIONS W O.R. PROCEDURE SOI 2	6,941	29,158	29,984	1.27404	102.83
748	POST-OP, POST-TRAUMA, OTHER DEVICE INFECTIONS W O.R. PROCEDURE SOI 3	4,929	57,117	64,296	2.49563	112.57
749	INFECTIOUS & PARASITIC DISEASES SOI 4	64,800	46,569	57,333	2.03476	123.12

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
750	SEPTICEMIA & DISSEMINATED INFECTIONS SOI 1	2,790	10,654	11,893	0.46553	111.63
751	SEPTICEMIA & DISSEMINATED INFECTIONS SOI 2	65,569	15,538	16,091	0.67893	103.55
752	SEPTICEMIA & DISSEMINATED INFECTIONS SOI 3	101,534	24,439	26,872	1.06781	109.96
753	POST-OPERATIVE, POST-TRAUMATIC, OTHER DEVICE INFECTIONS SOI 1	7,900	11,419	11,111	0.49892	97.30
754	POST-OPERATIVE, POST-TRAUMATIC, OTHER DEVICE INFECTIONS SOI 2	19,123	15,353	15,592	0.67082	101.56
755	POST-OPERATIVE, POST-TRAUMATIC, OTHER DEVICE INFECTIONS SOI 3	9,870	25,536	29,891	1.11576	117.05
756	FEVER SOI 1	2,156	9,183	8,667	0.40124	94.38
757	FEVER SOI 2	11,217	11,247	10,264	0.49144	91.25
758	FEVER SOI 3	5,392	16,756	17,171	0.73215	102.47
759	VIRAL ILLNESS SOI 1	1,437	7,880	7,150	0.34432	90.73
760	VIRAL ILLNESS SOI 2	6,317	8,983	8,025	0.39248	89.34
761	VIRAL ILLNESS SOI 3	3,330	15,126	16,720	0.66090	110.54
762	OTHER INFECTIOUS & PARASITIC DISEASES SOI 1	4,707	14,967	13,954	0.65397	93.23
763	OTHER INFECTIOUS & PARASITIC DISEASES SOI 2	7,483	21,695	22,102	0.94792	101.88
764	OTHER INFECTIOUS & PARASITIC DISEASES SOI 3	3,278	25,618	28,032	1.11937	109.42
765	MENTAL ILLNESS DIAGNOSIS W O.R. PROCEDURE SOI 1	131	19,671	17,890	0.85949	90.94
766	MENTAL ILLNESS DIAGNOSIS W O.R. PROCEDURE SOI 2	373	26,529	22,338	1.15915	84.20
767	MENTAL ILLNESS DIAGNOSIS W O.R. PROCEDURE SOI 3	261	57,763	159,709	2.52387	276.49
768	MENTAL ILLNESS DIAGNOSIS W O.R. PROCEDURE SOI 4	42	81,134	131,735	3.54502	162.37
769	MAJOR DEPRESSIVE, SCHIZOPHRENIA & BIPOLAR DISORDERS SOI 1	20,867	8,545	8,420	0.37335	98.54
770	MAJOR DEPRESSIVE, SCHIZOPHRENIA & BIPOLAR DISORDERS SOI 2	39,615	10,136	10,258	0.44286	101.20
771	MAJOR DEPRESSIVE, SCHIZOPHRENIA & BIPOLAR DISORDERS SOI 3	4,286	15,216	16,944	0.66484	111.36
772	MAJOR DEPRESSIVE, SCHIZOPHRENIA & BIPOLAR DISORDERS SOI 4	654	26,060	23,043	1.13866	88.42
773	ORGANIC MENTAL HEALTH DISTURBANCES SOI 1	5,037	9,600	12,363	0.41946	128.78
774	ORGANIC MENTAL HEALTH DISTURBANCES SOI 2	13,503	11,407	11,609	0.49842	101.77
775	ORGANIC MENTAL HEALTH DISTURBANCES SOI 3	4,548	16,287	17,812	0.71165	109.36
776	ORGANIC MENTAL HEALTH DISTURBANCES SOI 4	266	34,460	33,167	1.50568	96.25
777	OTHER MENTAL HEALTH DISORDERS SOI 1	8,124	7,108	6,656	0.31055	93.64
778	OTHER MENTAL HEALTH DISORDERS SOI 2	11,224	9,119	8,404	0.39845	92.16
779	OTHER MENTAL HEALTH DISORDERS SOI 3	3,204	13,694	13,836	0.59833	101.04
780	OTHER MENTAL HEALTH DISORDERS SOI 4	183	33,928	41,822	1.48245	123.26
781	DRUG & ALCOHOL ABUSE OR DEPENDENCE, LEFT AMA SOI 1 & 2	4,775	4,126	4,260	0.18030	103.24
782	DRUG & ALCOHOL ABUSE OR DEPENDENCE, LEFT AMA SOI 3 & 4	367	9,081	9,892	0.39678	108.93
783	DRUG ABUSE & DEPENDENCE DIAGNOSES SOI 1	11,408	6,031	5,804	0.26352	96.24
784	DRUG ABUSE & DEPENDENCE DIAGNOSES SOI 2	32,660	8,141	7,960	0.35572	97.77
785	DRUG ABUSE & DEPENDENCE DIAGNOSES SOI 3	8,029	14,000	14,793	0.61171	105.67
786	DRUG ABUSE & DEPENDENCE DIAGNOSES SOI 4	765	44,098	48,684	1.92682	110.40
787	O.R. PROCEDURE FOR OTHER COMPLICATIONS OF TREATMENT SOI 1	3,623	15,826	15,137	0.69149	95.65
788	O.R. PROCEDURE FOR OTHER COMPLICATIONS OF TREATMENT SOI 2	8,425	23,151	22,024	1.01153	95.14

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
789	O.R. PROCEDURE FOR OTHER COMPLICATIONS OF TREATMENT SOI 3	4,353	42,960	45,570	1.87708	106.07
790	O.R. PROCEDURE FOR OTHER COMPLICATIONS OF TREATMENT SOI 4	1,608	103,258	110,013	4.51170	106.54
791	INJURIES, POISONINGS & TOXIC EFFECTS OF DRUGS DIAGNOSES SOI 4	5,447	41,801	47,376	1.82642	113.34
792	ALLERGIC REACTIONS SOI 1	2,052	4,929	4,365	0.21539	88.54
793	ALLERGIC REACTIONS SOI 2	3,039	7,378	7,659	0.32239	103.81
794	ALLERGIC REACTIONS SOI 3	994	16,382	18,910	0.71580	115.43
795	POISONING OF MEDICINAL AGENTS SOI 1	4,529	6,061	5,043	0.26483	83.21
796	POISONING OF MEDICINAL AGENTS SOI 2	20,493	8,172	7,551	0.35708	92.40
797	POISONING OF MEDICINAL AGENTS SOI 3	11,483	14,502	14,572	0.63366	100.48
798	OTHER COMPLICATIONS OF TREATMENT SOI 1	6,956	8,240	7,520	0.36005	91.26
799	OTHER COMPLICATIONS OF TREATMENT SOI 2	14,682	11,680	13,831	0.51034	118.42
800	OTHER COMPLICATIONS OF TREATMENT SOI 3	7,191	20,409	26,865	0.89175	131.63
801	OTHER INJURY, POISONING & TOXIC EFFECT DIAGNOSES SOI 1	2,353	7,862	7,567	0.34353	96.25
802	OTHER INJURY, POISONING & TOXIC EFFECT DIAGNOSES SOI 2	5,148	9,158	9,243	0.40013	100.94
803	OTHER INJURY, POISONING & TOXIC EFFECT DIAGNOSES SOI 3	2,744	15,712	17,510	0.68650	111.45
804	BURN PROCEDURES SOI 4	261	191,142	207,934	8.35168	108.79
805	EXTENSIVE 3RD DEGREE OR FULL THICKNESS BURNS W SKIN GRAFT SOI 1	149	19,853	16,969	0.86747	85.47
806	EXTENSIVE 3RD DEGREE OR FULL THICKNESS BURNS W SKIN GRAFT SOI 2	591	34,972	36,562	1.52807	104.54
807	EXTENSIVE 3RD DEGREE OR FULL THICKNESS BURNS W SKIN GRAFT SOI 3	443	81,568	92,447	3.56402	113.34
808	BURN DIAGNOSES SOI 4	228	64,151	82,731	2.80299	128.96
809	EXTENSIVE 3RD DEGREE OR FULL THICKNESS BURNS W/O SKIN GRAFT SOI 1	86	11,654	12,965	0.50919	111.25
810	EXTENSIVE 3RD DEGREE OR FULL THICKNESS BURNS W/O SKIN GRAFT SOI 2	425	12,890	14,971	0.56321	116.15
811	EXTENSIVE 3RD DEGREE OR FULL THICKNESS BURNS W/O SKIN GRAFT SOI 3	380	21,097	26,616	0.92181	126.16
812	PARTIAL THICKNESS BURNS W OR W/O SKIN GRAFT SOI 1	615	9,239	14,564	0.40367	157.64
813	PARTIAL THICKNESS BURNS W OR W/O SKIN GRAFT SOI 2	1,076	14,186	29,984	0.61982	211.37
814	PARTIAL THICKNESS BURNS W OR W/O SKIN GRAFT SOI 3	582	20,889	26,792	0.91270	128.26
815	PROC W DIAG OF REHAB, AFTERCARE OR OTH CONTACT W HEALTH SERVICE SOI 1	1,580	15,359	12,914	0.67110	84.08
816	PROC W DIAG OF REHAB, AFTERCARE OR OTH CONTACT W HEALTH SERVICE SOI 2	845	24,092	23,200	1.05269	96.30
817	PROCW DIAG OF REHAB, AFTERCARE OR OTH CONTACT W HEALTH SERVICE SOI 3	217	41,843	42,891	1.82829	102.50
818	PROC W DIAG OF REHAB, AFTERCARE OR OTH CONTACT W HEALTH SERVICE SOI 4	41	85,847	82,328	3.75096	95.90
819	REHAB / AFTERCARE / CONVALESCENCE EXCEPT NEONATAL AFTERCARE SOI 4	451	36,028	46,596	1.57422	129.33
820	REHABILITATION SOI 1	564	11,441	9,211	0.49991	80.51
821	REHABILITATION SOI 2	1,343	13,960	11,477	0.60997	82.21
822	REHABILITATION SOI 3	612	21,089	18,962	0.92146	89.91
823	SIGNS, SYMPTOMS & OTHER FACTORS INFLUENCING HEALTH STATUS SOI 1	5,800	7,196	7,997	0.31442	111.14
824	SIGNS, SYMPTOMS & OTHER FACTORS INFLUENCING HEALTH STATUS SOI 2	24,719	9,249	8,508	0.40414	91.98
825	SIGNS, SYMPTOMS & OTHER FACTORS INFLUENCING HEALTH STATUS SOI 3	6,284	14,591	16,281	0.63756	111.58
826	OTHER AFTERCARE & CONVALESCENCE SOI 1	633	6,334	6,430	0.27677	101.52
827	OTHER AFTERCARE & CONVALESCENCE SOI 2	1,219	8,975	10,639	0.39215	118.54

SUMMARY STATISTICS FOR CONSOLIDATED SEVERITY-ADJUSTED DRGS

CSA DRG	Consolidated Severity-Adjusted DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
828	OTHER AFTERCARE & CONVALESCENCE SOI 3	333	17,644	25,563	0.77094	144.88
829	HIV DIAGNOSES SOI 4	2,998	61,154	69,052	2.67205	112.91
830	HIV W MULTIPLE MAJOR HIV RELATED CONDITIONS SOI 1 & 2	217	19,283	17,745	0.84256	92.02
831	HIV W MULTIPLE MAJOR HIV RELATED CONDITIONS SOI 3	1,531	36,183	41,587	1.58096	114.94
832	HIV W MAJOR HIV RELATED CONDITION SOI 1 & 2	1,674	16,493	16,973	0.72064	102.91
833	HIV W MAJOR HIV RELATED CONDITION SOI 3	4,441	26,536	32,469	1.15944	122.36
834	HIV W MULTIPLE SIGNIFICANT HIV RELATED CONDITIONS SOI 1 & 2	1,513	21,229	23,087	0.92758	108.75
835	HIV W MULTIPLE SIGNIFICANT HIV RELATED CONDITIONS SOI 3	1,005	30,784	36,875	1.34508	119.79
836	HIV W ONE SIGNIF HIV COND OR W/O SIGNIF RELATED COND SOI 1	915	11,035	12,619	0.48215	114.36
837	HIV W ONE SIGNIF HIV COND OR W/O SIGNIF RELATED COND SOI 2	5,258	13,878	14,766	0.60638	106.40
838	HIV W ONE SIGNIF HIV COND OR W/O SIGNIF RELATED COND SOI 3	1,952	21,442	27,431	0.93689	127.93
839	MULTIPLE SIGNIFICANT TRAUMA PROCEDURES SOI 4	1,884	106,838	98,269	4.66816	91.98
840	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA SOI 1 & 2	57	53,311	34,737	2.32934	65.16
841	CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA SOI 3	156	69,270	49,786	3.02666	71.87
842	EXTENSIVE ABDOMINAL/THORACIC PROCS FOR MULT SIGNIFICANT TRAUMA SOI 1 & 2	52	36,346	30,115	1.58809	82.86
843	EXTENSIVE ABDOMINAL/THORACIC PROCS FOR MULT SIGNIFICANT TRAUMA SOI 3	293	55,906	47,625	2.44274	85.19
844	MUSCULOSKELETAL & OTHER PROCS FOR MULTIPLE SIGNIFICANT TRAUMA SOI 1 & 2	1,568	31,283	20,964	1.36686	67.01
845	MUSCULOSKELETAL & OTHER PROCS FOR MULTIPLE SIGNIFICANT TRAUMA SOI 3	2,424	54,386	45,948	2.37631	84.49
846	MULTIPLE SIGNIFICANT TRAUMA W/O O.R. PROCEDURE SOI 1 & 2	1,936	17,640	16,499	0.77076	93.53
847	MULTIPLE SIGNIFICANT TRAUMA W/O O.R. PROCEDURE SOI 3	2,324	30,604	28,374	1.33722	92.71
848	MULTIPLE SIGNIFICANT TRAUMA W/O O.R. PROCEDURE SOI 4	826	68,674	73,265	3.00061	106.69
987	EXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 1	1,007	26,575	23,629	1.16116	88.92
988	EXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 2	5,398	42,458	37,282	1.85515	87.81
989	EXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 3	10,618	66,823	61,947	2.91972	92.70
990	EXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 4	6,820	120,495	113,932	5.26486	94.55
991	NON MAJOR PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 4	9,565	97,441	123,634	4.25753	126.88
992	MODERATELY EXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 1	2,778	20,548	24,889	0.89780	121.13
993	MODERATELY EXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 2	11,903	31,314	28,001	1.36822	89.42
994	MODERATELY EXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 3	15,336	52,263	50,019	2.28357	95.71
995	NONEXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 1	5,001	13,506	13,075	0.59015	96.80
996	NONEXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 2	12,212	23,627	22,225	1.03236	94.06
997	NONEXTENSIVE PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS SOI 3	12,062	42,642	50,880	1.86319	119.32
999	UNGROUPABLE	37	10,369	11,267	0.45305	108.66

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
	Average Coefficient of Variation (Discharge Weighted) Across Medicare Modified APS-DRGs					89.67
	ALL DISCHARGES COMBINED	11,935,204	22,887	35,524	1.00000	155.22
0010	CRANIOTOMY WO CC	12,566	31,249	20,701	1.36537	66.25
0011	CRANIOTOMY W CC	14,403	43,767	32,905	1.91235	75.18
0012	CRANIOTOMY W MCC	6,123	80,263	67,230	3.50699	83.76
0060	CARPAL TUNNEL RELEASE WO CC	253	10,482	7,060	0.45799	67.35
0061	CARPAL TUNNEL RELEASE W CC	139	14,185	12,989	0.61979	91.57
0062	CARPAL TUNNEL RELEASE W MCC	11	31,211	30,900	1.36374	99.00
0070	PERIPH&CRAN NERV&OTH NRV SYS PROC WO CC	4,726	27,459	19,513	1.19979	71.06
0071	PERIPH&CRAN NERV&OTH NRV SYS PROC W CC	10,172	32,811	30,035	1.43363	91.54
0072	PERIPH&CRAN NERV&OTH NRV SYS PROC W MCC	3,763	64,954	76,082	2.83808	117.13
0090	SPINAL DISORDERS & INJURIES WO CC	609	13,365	12,767	0.58399	95.52
0091	SPINAL DISORDERS & INJURIES W CC	925	20,355	21,222	0.88940	104.26
0092	SPINAL DISORDERS & INJURIES W MCC	377	37,827	37,783	1.65280	99.88
0100	NERVOUS SYSTEM NEOPLASMS WO CC	5,017	13,878	12,219	0.60636	88.05
0101	NERVOUS SYSTEM NEOPLASMS W CC	14,117	17,503	16,474	0.76476	94.12
0102	NERVOUS SYSTEM NEOPLASMS W MCC	3,218	26,847	28,358	1.17305	105.63
0120	DEGENERATIVE NERV SYS DISORDERS WO CC	21,846	10,782	11,159	0.47112	103.50
0121	DEGENERATIVE NERV SYS DISORDERS W CC	25,778	13,572	14,058	0.59299	103.59
0122	DEGENERATIVE NERV SYS DISORDERS W MCC	5,634	26,534	36,398	1.15937	137.18
0130	MULTIPLE SCLEROSIS& CEREB ATAXIA WO CC	3,408	10,379	10,769	0.45348	103.77
0131	MULTIPLE SCLEROSIS& CEREB ATAXIA W CC	3,295	14,255	14,541	0.62287	102.00
0132	MULTIPLE SCLEROSIS& CEREB ATAXIA W MCC	501	27,651	40,980	1.20819	148.20
0140	INTRACRAN HEM OR CEREBRAL INFARCT WO CC	87,902	13,972	11,083	0.61047	79.32
0141	INTRACRAN HEM OR CEREBRAL INFARCT W CC	101,792	18,266	15,987	0.79812	87.52
0142	INTRACRAN HEM OR CEREBRAL INFARCT W MCC	40,725	31,934	35,309	1.39531	110.57
0150	NONSPEC CVA & PREC OCC WO INFARCT WO CC	32,144	11,632	8,829	0.50824	75.90
0151	NONSPEC CVA & PREC OCC WO INFARCT W CC	34,716	14,592	12,162	0.63760	83.34
0152	NONSPEC CVA & PREC OCC WO INFARCT W MCC	7,893	25,038	29,363	1.09399	117.27
0160	NONSPEC CEREBROVASC DISORD WO CC	4,449	11,696	9,653	0.51103	82.54
0161	NONSPEC CEREBROVASC DISORD W CC	10,717	17,479	16,603	0.76373	94.99
0162	NONSPEC CEREBROVASC DISORD W MCC	3,753	31,926	33,943	1.39497	106.32
0180	CRANIAL & PERIPH NERVE DISORDERS WO CC	12,213	11,242	11,325	0.49121	100.74

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
0181	CRANIAL & PERIPH NERVE DISORDERS W CC	24,882	14,307	14,141	0.62513	98.84
0182	CRANIAL & PERIPH NERVE DISORDERS W MCC	3,857	26,755	32,784	1.16902	122.53
0200	NERV SYS INF EXC VIRAL MENINGITIS WO CC	1,323	25,479	32,261	1.11327	126.62
0201	NERV SYS INF EXC VIRAL MENINGITIS W CC	2,732	33,664	33,108	1.47089	98.35
0202	NERV SYS INF EXC VIRAL MENINGITIS W MCC	2,380	57,748	54,433	2.52321	94.26
0210	VIRAL MENINGITIS WO CC	835	13,872	10,276	0.60613	74.08
0211	VIRAL MENINGITIS W CC	957	22,122	19,741	0.96658	89.24
0212	VIRAL MENINGITIS W MCC	385	42,053	37,351	1.83743	88.82
0220	HYPERTENSIVE ENCEPHALOPATHY WO CC	893	10,745	8,171	0.46948	76.05
0221	HYPERTENSIVE ENCEPHALOPATHY W CC	1,786	16,803	15,171	0.73420	90.29
0222	HYPERTENSIVE ENCEPHALOPATHY W MCC	576	31,162	29,218	1.36158	93.76
0230	NONTRAUMATIC STUPOR & COMA WO CC	2,917	9,513	8,504	0.41567	89.40
0231	NONTRAUMATIC STUPOR & COMA W CC	6,293	11,727	10,445	0.51241	89.07
0232	NONTRAUMATIC STUPOR & COMA W MCC	1,413	19,632	24,466	0.85778	124.63
0240	SEIZURE & HEADACHE WO CC	35,195	9,957	8,895	0.43504	89.34
0241	SEIZURE & HEADACHE W CC	43,711	13,088	12,425	0.57188	94.93
0242	SEIZURE & HEADACHE W MCC	11,730	27,508	31,481	1.20192	114.44
0270	TRAUM STUPOR & COMA,COMA >1 HR WO CC	2,000	13,440	13,814	0.58725	102.78
0271	TRAUM STUPOR & COMA,COMA >1 HR W CC	2,148	20,161	25,709	0.88089	127.52
0272	TRAUM STUPOR & COMA,COMA >1 HR W MCC	1,173	36,849	44,534	1.61007	120.86
0280	TRAUM STUPOR&COMA,COMA<1HR WO CC	8,634	11,859	11,337	0.51817	95.60
0281	TRAUM STUPOR&COMA,COMA<1HR W CC	11,696	18,009	17,460	0.78689	96.95
0282	TRAUM STUPOR&COMA,COMA<1HR W MCC	3,172	35,858	40,789	1.56675	113.75
0310	CONCUSSION WO CC	2,920	10,381	8,473	0.45357	81.63
0311	CONCUSSION W CC	3,637	14,013	13,130	0.61229	93.69
0312	CONCUSSION W MCC	500	30,364	40,351	1.32672	132.89
0340	OTHER DISORDERS OF NERVOUS SYSTEM WO CC	10,445	10,132	8,290	0.44271	81.82
0341	OTHER DISORDERS OF NERVOUS SYSTEM W CC	18,640	13,526	13,495	0.59100	99.77
0342	OTHER DISORDERS OF NERVOUS SYSTEM W MCC	4,399	28,037	35,574	1.22505	126.88
0370	ORBITAL PROCEDURES WO CC	563	13,376	10,941	0.58444	81.80
0371	ORBITAL PROCEDURES W CC	560	20,034	18,953	0.87538	94.60
0372	ORBITAL PROCEDURES W MCC	91	48,544	54,094	2.12109	111.43
0390	PRIMARY IRIS & LENS PROCEDURES WO CC	242	9,319	6,889	0.40720	73.92
0393	PRIMARY IRIS & LENS PROCEDURES W CC OR MCC	240	13,756	17,891	0.60104	130.06
0400	EXTRAOCLR PROCS EXC ORBIT WO CC	803	13,964	9,435	0.61012	67.57

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
0403	EXTRAOCLR PROCS EXC ORBIT W CC OR MCC	549	17,097	15,108	0.74703	88.37
0420	INTRAOCULAR PROCS EXC IRIS & LENS WO CC	1,473	10,402	6,536	0.45451	62.83
0423	INTRAOCULAR PROCS EXC IRIS & LENS W CC OR MCC	1,008	15,033	13,027	0.65685	86.66
0440	ACUTE MAJOR EYE INFECTIONS WO CC	552	8,143	7,579	0.35578	93.08
0441	ACUTE MAJOR EYE INFECTIONS W CC	537	11,739	10,185	0.51294	86.76
0442	ACUTE MAJOR EYE INFECTIONS W MCC	58	27,319	37,322	1.19366	136.62
0450	NEUROLOGICAL EYE DISORDERS WO CC	1,640	10,471	8,054	0.45750	76.92
0453	NEUROLOGICAL EYE DISORDERS W CC OR MCC	1,128	13,639	20,009	0.59592	146.71
0460	OTHER DISORDERS OF EYE WO CC	1,878	8,731	8,272	0.38149	94.74
0461	OTHER DISORDERS OF EYE W CC	2,952	11,267	10,690	0.49229	94.88
0462	OTHER DISORDERS OF EYE W MCC	335	20,104	24,889	0.87844	123.80
0490	MAJOR HEAD & NECK PROCEDURES WO CC	937	21,372	16,637	0.93383	77.85
0491	MAJOR HEAD & NECK PROCEDURES W CC	1,311	24,192	19,610	1.05704	81.06
0492	MAJOR HEAD & NECK PROCEDURES W MCC	191	60,566	55,027	2.64634	90.85
0510	SALIVARY GLAND PROCEDURES WO CC	1,598	12,015	7,339	0.52498	61.08
0511	SALIVARY GLAND PROCEDURES W CC	656	15,543	14,655	0.67914	94.28
0512	SALIVARY GLAND PROCEDURES W MCC	38	46,280	53,187	2.02216	114.92
0520	CLEFT LIP & PALATE REPAIR WO CC	235	11,154	6,418	0.48738	57.54
0521	CLEFT LIP & PALATE REPAIR W CC	75	14,215	10,051	0.62109	70.71
0522	CLEFT LIP & PALATE REPAIR W MCC	14	43,680	38,323	1.90854	87.74
0530	SINUS & MASTOID PROCS WO CC	1,184	14,563	10,965	0.63633	75.29
0531	SINUS & MASTOID PROCS W CC	854	23,126	22,187	1.01044	95.94
0532	SINUS & MASTOID PROCS W MCC	187	48,719	49,543	2.12871	101.69
0560	MISC EAR,NOSE,MOUTH& THROAT PROCS WO CC	1,574	11,034	8,276	0.48211	75.01
0561	MISC EAR,NOSE,MOUTH& THROAT PROCS W CC	1,054	16,832	16,729	0.73546	99.39
0562	MISC EAR,NOSE,MOUTH& THROAT PROCS W MCC	187	41,989	46,387	1.83466	110.47
0610	MYRINGOTOMY W TUBE INSERT WO CC	92	12,280	8,511	0.53655	69.31
0613	MYRINGOTOMY W TUBE INSERT W CC OR MCC	119	26,461	25,057	1.15616	94.69
0630	OTH EAR,NOSE,MOUTH,THROAT O.R. WO CC	1,245	16,419	13,643	0.71739	83.09
0631	OTH EAR,NOSE,MOUTH,THROAT O.R. W CC	1,326	21,590	19,314	0.94336	89.46
0632	OTH EAR,NOSE,MOUTH,THROAT O.R. W MCC	266	51,181	55,529	2.23629	108.49
0640	EAR,NOSE,MOUTH,THROAT MALIGNANCY WO CC	721	10,902	12,563	0.47633	115.24
0641	EAR,NOSE,MOUTH,THROAT MALIGNANCY W CC	1,935	17,444	22,088	0.76217	126.63
0642	EAR,NOSE,MOUTH,THROAT MALIGNANCY W MCC	644	28,743	30,104	1.25587	104.74
0650	DYSEQUILIBRIUM WO CC	25,377	8,726	6,732	0.38126	77.15

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
0651	DYSEQUILIBRIUM W CC	14,511	10,409	8,496	0.45482	81.62
0652	DYSEQUILIBRIUM W MCC	856	16,174	24,557	0.70669	151.83
0660	EPISTAXIS & EPIGLOTTITIS WO CC	3,149	7,084	7,241	0.30952	102.22
0661	EPISTAXIS & EPIGLOTTITIS W CC	4,581	9,588	10,292	0.41892	107.35
0662	EPISTAXIS & EPIGLOTTITIS W MCC	582	22,020	26,834	0.96212	121.86
0680	OTITIS MEDIA & URI WO CC	8,429	7,624	6,017	0.33314	78.92
0681	OTITIS MEDIA & URI W CC	12,136	10,335	10,212	0.45158	98.80
0682	OTITIS MEDIA & URI W MCC	1,340	17,475	19,894	0.76354	113.84
0730	OTH EAR,NOSE,MOUTH,THROAT WO CC	3,543	9,416	8,289	0.41143	88.03
0731	OTH EAR,NOSE,MOUTH,THROAT W CC	5,511	13,111	12,981	0.57285	99.01
0732	OTH EAR,NOSE,MOUTH,THROAT W MCC	1,450	21,933	23,473	0.95834	107.02
0750	MAJOR CHEST PROCEDURES WO CC	9,115	26,645	18,098	1.16421	67.92
0751	MAJOR CHEST PROCEDURES W CC	23,508	38,784	29,003	1.69461	74.78
0752	MAJOR CHEST PROCEDURES W MCC	11,562	82,505	77,792	3.60496	94.29
0760	OTHER RESP SYSTEM O.R. PROCEDURES WO CC	3,714	20,212	17,396	0.88313	86.07
0761	OTHER RESP SYSTEM O.R. PROCEDURES W CC	25,511	32,279	28,557	1.41037	88.47
0762	OTHER RESP SYSTEM O.R. PROCEDURES W MCC	19,374	61,743	79,656	2.69779	129.01
0780	PULMONARY EMBOLISM WO CC	7,972	14,294	10,008	0.62455	70.01
0781	PULMONARY EMBOLISM W CC	27,747	18,212	14,105	0.79574	77.45
0782	PULMONARY EMBOLISM W MCC	9,002	25,646	22,466	1.12059	87.60
0790	RESP INFECT & INFLAM WO CC	14,782	14,537	14,052	0.63516	96.66
0791	RESP INFECT & INFLAM W CC	98,798	20,981	20,534	0.91676	97.87
0792	RESP INFECT & INFLAM W MCC	61,580	30,913	32,380	1.35068	104.75
0820	RESPIRATORY NEOPLASMS WO CC	5,373	13,420	12,281	0.58635	91.51
0821	RESPIRATORY NEOPLASMS W CC	38,361	19,474	19,334	0.85089	99.28
0822	RESPIRATORY NEOPLASMS W MCC	20,317	27,371	28,085	1.19594	102.61
0830	MAJOR CHEST TRAUMA WO CC	2,050	9,676	8,183	0.42278	84.57
0831	MAJOR CHEST TRAUMA W CC	5,328	13,823	12,582	0.60399	91.02
0832	MAJOR CHEST TRAUMA W MCC	1,048	23,964	22,668	1.04706	94.59
0870	PULMONARY EDEMA & RESP FAILURE WO CC	1,658	11,815	11,986	0.51623	101.45
0873	PULMONARY EDEMA & RESP FAILURE W CC OR MCC	78,952	21,365	25,213	0.93350	118.01
0880	CHRONIC OBSTR PULMONARY DISEASE WO CC	167,291	10,876	9,532	0.47519	87.65
0881	CHRONIC OBSTR PULMONARY DISEASE W CC	183,391	14,173	13,212	0.61927	93.22
0882	CHRONIC OBSTR PULMONARY DISEASE W MCC	57,098	20,421	23,490	0.89228	115.03
0890	SIMP PNEU,PLRSY,INSTIT DIS WO CC	84,127	10,255	8,556	0.44808	83.43

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
0891	SIMP PNEU,PLRSY,INSTIT DIS W CC	438,616	14,941	13,765	0.65284	92.13
0892	SIMP PNEU,PLRSY,INSTIT DIS W MCC	82,255	23,599	24,680	1.03114	104.58
0940	PNEUMOTHORAX & PLEURAL EFFUSION WO CC	5,926	10,938	9,980	0.47793	91.24
0941	PNEUMOTHORAX & PLEURAL EFFUSION W CC	23,487	16,308	15,668	0.71257	96.07
0942	PNEUMOTHORAX & PLEURAL EFFUSION W MCC	8,731	26,114	25,943	1.14102	99.34
0960	BRONCHITIS & ASTHMA WO CC	36,143	8,631	7,412	0.37710	85.88
0961	BRONCHITIS & ASTHMA W CC	42,607	11,187	10,305	0.48881	92.12
0962	BRONCHITIS & ASTHMA W MCC	6,336	15,334	16,416	0.67000	107.06
0990	RESPIRATORY SIGNS & SYMPTOMS WO CC	9,791	8,712	6,928	0.38066	79.52
0991	RESPIRATORY SIGNS & SYMPTOMS W CC	15,976	10,750	9,601	0.46972	89.31
0992	RESPIRATORY SIGNS & SYMPTOMS W MCC	2,333	15,399	18,610	0.67284	120.86
1010	OTHER RESP SYSTEM DIAGNOSES WO CC	7,221	8,939	7,233	0.39058	80.91
1011	OTHER RESP SYSTEM DIAGNOSES W CC	16,771	12,390	11,589	0.54136	93.54
1012	OTHER RESP SYSTEM DIAGNOSES W MCC	4,011	20,150	22,622	0.88042	112.27
1030	HEART TRANSPL OR IMPL HEART ASST WO CC	24	144,342	77,122	6.30682	53.43
1031	HEART TRANSPL OR IMPL HEART ASST W CC	274	206,804	150,325	9.03605	72.69
1032	HEART TRANSPL OR IMPL HEART ASST W MCC	451	408,947	350,957	17.86840	85.82
1040	CARD VALV OTH MAJ CARD PR W CATH WO CC	2,321	81,879	39,942	3.57760	48.78
1041	CARD VALV OTH MAJ CARD PR W CATH W CC	10,848	103,961	56,834	4.54242	54.67
1042	CARD VALV OTH MAJ CARD PR W CATH W MCC	7,545	161,781	111,480	7.06880	68.91
1050	CARD VALV OTH MAJ CARD PR WO CATH WO CC	5,796	65,001	32,787	2.84014	50.44
1051	CARD VALV OTH MAJ CARD PR WO CATH W CC	17,829	79,936	45,617	3.49271	57.07
1052	CARD VALV OTH MAJ CARD PR WO CATH W MCC	7,714	135,226	96,263	5.90853	71.19
1060	CORONARY BYPASS WITH PTCA WO CC	622	81,583	36,517	3.56465	44.76
1061	CORONARY BYPASS WITH PTCA W CC	1,519	96,586	45,360	4.22021	46.96
1062	CORONARY BYPASS WITH PTCA W MCC	1,340	138,282	84,165	6.04205	60.86
1080	OTHER CARDIOTHORACIC PROCEDURES WO CC	1,636	58,186	32,198	2.54235	55.34
1081	OTHER CARDIOTHORACIC PROCEDURES W CC	3,760	76,605	46,105	3.34714	60.19
1082	OTHER CARDIOTHORACIC PROCEDURES W MCC	2,434	126,936	90,013	5.54629	70.91
1100	MAJOR CARDIOVASCULAR PROCS WO CC	14,105	39,373	24,112	1.72034	61.24
1101	MAJOR CARDIOVASCULAR PROCS W CC	32,126	46,996	33,024	2.05344	70.27
1102	MAJOR CARDIOVASCULAR PROCS W MCC	19,946	87,384	73,110	3.81811	83.67
1130	AMPUT CIRC DISOR EXC UP LIMB,TOE WO CC	2,485	19,972	21,490	0.87267	107.60
1131	AMPUT CIRC DISOR EXC UP LIMB,TOE W CC	21,994	34,751	37,438	1.51841	107.73
1132	AMPUT CIRC DISOR EXC UP LIMB,TOE W MCC	12,145	66,057	75,719	2.88629	114.63

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
1140	UPPR LIMB,TOE AMPUT CIRC DISOR WO CC	538	13,618	13,535	0.59503	99.39
1141	UPPR LIMB,TOE AMPUT CIRC DISOR W CC	6,552	22,289	22,346	0.97387	100.26
1142	UPPR LIMB,TOE AMPUT CIRC DISOR W MCC	1,329	45,752	50,278	1.99908	109.89
1170	CARD PACEMKR REVIS EX DEVICE REPL WO CC	1,902	13,094	10,966	0.57212	83.75
1171	CARD PACEMKR REVIS EX DEVICE REPL W CC	2,615	20,279	19,444	0.88607	95.88
1172	CARD PACEMKR REVIS EX DEVICE REPL W MCC	555	49,805	46,335	2.17615	93.03
1180	CARDIAC PACEMAKER DEVICE REPLACE WO CC	3,352	21,752	12,137	0.95042	55.80
1181	CARDIAC PACEMAKER DEVICE REPLACE W CC	3,801	26,971	16,946	1.17844	62.83
1182	CARDIAC PACEMAKER DEVICE REPLACE W MCC	393	48,182	40,661	2.10525	84.39
1200	OTHER CIRCULATORY SYST O.R. PROCS WO CC	1,816	18,695	16,451	0.81687	88.00
1201	OTHER CIRCULATORY SYST O.R. PROCS W CC	24,247	26,342	27,543	1.15098	104.56
1202	OTHER CIRCULATORY SYST O.R. PROCS W MCC	10,649	62,351	86,839	2.72432	139.27
1210	CIRC DISOR W AMI DISCH ALIVE WO CC	46,611	13,487	10,817	0.58930	80.21
1211	CIRC DISOR W AMI DISCH ALIVE W CC	107,971	18,213	15,427	0.79580	84.70
1212	CIRC DISOR W AMI DISCH ALIVE W MCC	62,347	32,179	31,419	1.40600	97.64
1230	CIRC DISOR W AMI, EXPIRED WO CC	1,452	10,146	11,290	0.44332	111.27
1231	CIRC DISOR W AMI, EXPIRED W CC	10,663	14,136	14,902	0.61767	105.41
1232	CIRC DISOR W AMI, EXPIRED W MCC	20,989	30,275	39,493	1.32281	130.45
1240	CIRC DIS EX AMI W CATH & COMP DX WO CC	63,947	17,756	11,618	0.77583	65.43
1241	CIRC DIS EX AMI W CATH & COMP DX W CC	51,770	23,259	17,480	1.01627	75.15
1242	CIRC DIS EX AMI W CATH & COMP DX W MCC	13,053	41,041	39,022	1.79324	95.08
1250	CIRC DIS EX AMI W CATH WO COMP DX WO CC	61,439	15,653	9,227	0.68394	58.95
1251	CIRC DIS EX AMI W CATH WO COMP DX W CC	31,221	18,739	12,049	0.81876	64.30
1252	CIRC DIS EX AMI W CATH WO COMP DX W MCC	2,651	28,451	22,590	1.24312	79.40
1260	ACUTE & SUBACUTE ENDOCARDITIS WO CC	408	19,488	18,263	0.85151	93.71
1261	ACUTE & SUBACUTE ENDOCARDITIS W CC	1,950	28,835	26,435	1.25993	91.68
1262	ACUTE & SUBACUTE ENDOCARDITIS W MCC	3,346	50,104	50,897	2.18924	101.58
1270	HEART FAILURE & SHOCK WO CC	148,691	10,551	9,100	0.46101	86.25
1271	HEART FAILURE & SHOCK W CC	395,830	14,529	13,633	0.63484	93.83
1272	HEART FAILURE & SHOCK W MCC	138,186	26,171	29,374	1.14349	112.24
1280	DEEP VEIN THROMBOPHLEBITIS WO CC	2,168	8,184	7,581	0.35758	92.64
1281	DEEP VEIN THROMBOPHLEBITIS W CC	2,511	11,438	10,950	0.49976	95.73
1282	DEEP VEIN THROMBOPHLEBITIS W MCC	413	20,743	21,403	0.90635	103.18
1290	CARDIAC ARREST, UNEXPLAINED WO CC	407	7,204	5,800	0.31477	80.51
1291	CARDIAC ARREST, UNEXPLAINED W CC	882	9,527	8,546	0.41626	89.70

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
1292	CARDIAC ARREST, UNEXPLAINED W MCC	2,438	20,152	25,345	0.88050	125.77
1300	PERIPHERAL VASCULAR DISORDERS WO CC	30,662	9,074	8,440	0.39646	93.02
1301	PERIPHERAL VASCULAR DISORDERS W CC	68,077	13,172	13,318	0.57555	101.11
1302	PERIPHERAL VASCULAR DISORDERS W MCC	12,410	23,299	27,713	1.01802	118.95
1320	ATHEROSCLEROSIS WO CC	54,591	8,131	6,717	0.35529	82.61
1321	ATHEROSCLEROSIS W CC	62,075	10,227	9,177	0.44684	89.74
1322	ATHEROSCLEROSIS W MCC	5,229	18,848	25,719	0.82354	136.45
1340	HYPERTENSION WO CC	23,955	8,192	6,880	0.35792	83.98
1341	HYPERTENSION W CC	16,114	10,383	9,495	0.45366	91.45
1342	HYPERTENSION W MCC	1,672	19,441	22,233	0.84945	114.36
1350	CARD CONGEN & VALV DISOR WO CC	2,193	9,780	8,707	0.42734	89.03
1351	CARD CONGEN & VALV DISOR W CC	5,204	12,835	13,171	0.56079	102.62
1352	CARD CONGEN & VALV DISOR W MCC	1,052	23,443	25,929	1.02431	110.60
1380	CARD ARRHYTHMIA & CONDUCTN DISOR WO CC	110,509	8,605	7,363	0.37599	85.57
1381	CARD ARRHYTHMIA & CONDUCTN DISOR W CC	146,906	11,991	11,115	0.52391	92.70
1382	CARD ARRHYTHMIA & CONDUCTN DISOR W MCC	23,470	23,988	29,719	1.04812	123.89
1400	ANGINA PECTORIS WO CC	20,571	7,064	5,876	0.30866	83.18
1401	ANGINA PECTORIS W CC	15,867	8,571	7,311	0.37449	85.30
1402	ANGINA PECTORIS W MCC	1,148	14,117	15,750	0.61680	111.57
1410	SYNCOPE & COLLAPSE WO CC	77,989	9,565	7,544	0.41793	78.87
1411	SYNCOPE & COLLAPSE W CC	84,141	11,954	10,328	0.52233	86.39
1412	SYNCOPE & COLLAPSE W MCC	8,388	18,072	19,466	0.78963	107.72
1430	CHEST PAIN WO CC	137,596	8,080	5,863	0.35306	72.56
1431	CHEST PAIN W CC	101,167	9,779	8,144	0.42728	83.28
1432	CHEST PAIN W MCC	5,811	14,807	13,922	0.64695	94.03
1440	OTH CIRCULATORY SYSTEM DIAGNOSES WO CC	11,748	9,496	8,960	0.41490	94.35
1441	OTH CIRCULATORY SYSTEM DIAGNOSES W CC	57,831	14,550	14,969	0.63575	102.88
1442	OTH CIRCULATORY SYSTEM DIAGNOSES W MCC	34,255	30,204	43,051	1.31971	142.53
1480	MAJOR SMALL & LARGE BOWEL PROCS WO CC	31,202	24,017	16,454	1.04941	68.51
1481	MAJOR SMALL & LARGE BOWEL PROCS W CC	85,341	37,992	31,412	1.66000	82.68
1482	MAJOR SMALL & LARGE BOWEL PROCS W MCC	49,521	80,203	76,893	3.50434	95.87
1500	PERITONEAL ADHESIOLYSIS WO CC	7,114	21,580	15,190	0.94290	70.39
1501	PERITONEAL ADHESIOLYSIS W CC	14,119	34,405	27,330	1.50327	79.44
1502	PERITONEAL ADHESIOLYSIS W MCC	6,312	68,515	62,982	2.99369	91.92
1520	MINOR SMALL & LARGE BOWEL PROCS WO CC	2,721	17,458	11,657	0.76281	66.77

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
1521	MINOR SMALL & LARGE BOWEL PROCS W CC	3,467	25,399	19,943	1.10979	78.52
1522	MINOR SMALL & LARGE BOWEL PROCS W MCC	823	54,607	54,594	2.38596	99.98
1540	STOMACH,ESOPH & DUOD PROC WO CC	7,935	22,203	18,846	0.97015	84.88
1541	STOMACH,ESOPH & DUOD PROC W CC	14,195	42,178	37,476	1.84293	88.85
1542	STOMACH,ESOPH & DUOD PROC W MCC	12,030	90,826	92,821	3.96853	102.20
1570	ANAL & STOMAL PROCEDURES WO CC	5,055	10,881	8,249	0.47545	75.81
1571	ANAL & STOMAL PROCEDURES W CC	6,103	18,066	17,871	0.78938	98.92
1572	ANAL & STOMAL PROCEDURES W MCC	1,082	41,940	43,087	1.83252	102.73
1590	HERNIA PROC EXC ING,FEMOR WO CC	14,196	13,531	8,715	0.59124	64.41
1591	HERNIA PROC EXC ING,FEMOR W CC	14,179	19,202	16,379	0.83898	85.30
1592	HERNIA PROC EXC ING,FEMOR W MCC	2,450	44,231	44,160	1.93263	99.84
1610	ING & FEMORAL HERNIA PROC WO CC	7,068	11,302	8,034	0.49382	71.08
1611	ING & FEMORAL HERNIA PROC W CC	7,402	16,672	14,753	0.72848	88.49
1612	ING & FEMORAL HERNIA PROC W MCC	1,214	39,168	42,939	1.71140	109.63
1640	APPENDECTOMY W COMPLIC PRINC DX WO CC	3,110	19,399	11,811	0.84760	60.89
1641	APPENDECTOMY W COMPLIC PRINC DX W CC	3,969	28,857	19,309	1.26085	66.91
1642	APPENDECTOMY W COMPLIC PRINC DX W MCC	1,288	60,951	54,184	2.66316	88.90
1660	APPENDECTOMY WO COMPLIC PRINC DX WO CC	5,402	14,405	8,473	0.62942	58.82
1661	APPENDECTOMY WO COMPLIC PRINC DX W CC	3,502	20,364	15,348	0.88976	75.37
1662	APPENDECTOMY WO COMPLIC PRINC DX W MCC	603	44,066	45,557	1.92540	103.38
1680	MOUTH PROCEDURES WO CC	974	12,119	9,608	0.52952	79.28
1681	MOUTH PROCEDURES W CC	1,135	16,908	16,223	0.73876	95.95
1682	MOUTH PROCEDURES W MCC	188	43,992	39,509	1.92217	89.81
1700	OTHER DIGESTIVE SYSTEM O.R. PROCS WO CC	2,072	20,235	16,106	0.88416	79.59
1701	OTHER DIGESTIVE SYSTEM O.R. PROCS W CC	9,844	33,805	31,386	1.47706	92.84
1702	OTHER DIGESTIVE SYSTEM O.R. PROCS W MCC	6,740	63,967	68,676	2.79494	107.36
1720	DIGESTIVE MALIGNANCY WO CC	4,523	12,940	12,519	0.56538	96.75
1721	DIGESTIVE MALIGNANCY W CC	22,672	19,258	20,754	0.84146	107.77
1722	DIGESTIVE MALIGNANCY W MCC	7,515	31,935	38,548	1.39538	120.70
1740	G.I. HEMORRHAGE WO CC	82,073	10,557	8,726	0.46127	82.66
1741	G.I. HEMORRHAGE W CC	176,061	14,563	13,086	0.63632	89.86
1742	G.I. HEMORRHAGE W MCC	37,144	27,131	30,526	1.18546	112.51
1760	COMPLICATED PEPTIC ULCER WO CC	4,463	12,466	10,028	0.54470	80.44
1761	COMPLICATED PEPTIC ULCER W CC	7,697	16,716	14,255	0.73038	85.28
1762	COMPLICATED PEPTIC ULCER W MCC	2,197	30,845	36,351	1.34771	117.85

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
1770	UNCOMPLICATED PEPTIC ULCER WO CC	4,662	11,097	8,010	0.48486	72.18
1771	UNCOMPLICATED PEPTIC ULCER W CC	6,052	14,117	11,252	0.61683	79.70
1772	UNCOMPLICATED PEPTIC ULCER W MCC	667	23,215	30,823	1.01435	132.77
1790	INFLAMMATORY BOWEL DISEASE WO CC	4,357	12,455	12,654	0.54422	101.60
1791	INFLAMMATORY BOWEL DISEASE W CC	8,225	16,899	16,712	0.73838	98.89
1792	INFLAMMATORY BOWEL DISEASE W MCC	1,659	31,673	42,924	1.38391	135.52
1800	G.I. OBSTRUCTION WO CC	39,709	9,364	8,060	0.40915	86.07
1801	G.I. OBSTRUCTION W CC	61,875	13,576	13,598	0.59318	100.16
1802	G.I. OBSTRUCTION W MCC	14,848	26,140	32,397	1.14217	123.93
1820	ESPHGITIS,GE,MISC DIG DIS WO CC	143,051	9,282	7,799	0.40556	84.02
1821	ESPHGITIS,GE,MISC DIG DIS W CC	198,382	12,674	13,037	0.55380	102.86
1822	ESPHGITIS,GE,MISC DIG DIS W MCC	31,841	22,936	28,411	1.00215	123.87
1850	DENTAL & ORAL DISORDERS WO CC	1,974	8,959	8,124	0.39146	90.68
1851	DENTAL & ORAL DISORDERS W CC	3,676	13,787	15,181	0.60240	110.11
1852	DENTAL & ORAL DISORDERS W MCC	582	28,524	31,762	1.24634	111.35
1880	OTHER DIGESTIVE SYSTEM DX WO CC	20,470	10,332	10,551	0.45146	102.12
1881	OTHER DIGESTIVE SYSTEM DX W CC	61,511	15,089	15,569	0.65931	103.18
1882	OTHER DIGESTIVE SYSTEM DX W MCC	20,380	27,039	40,195	1.18143	148.66
1910	PANCREAS,LIVER & SHUNT PROCEDURES WO CC	1,989	27,689	20,836	1.20984	75.25
1911	PANCREAS,LIVER & SHUNT PROCEDURES W CC	6,224	43,063	36,677	1.88159	85.17
1912	PANCREAS,LIVER & SHUNT PROCEDURES W MCC	3,288	102,606	111,852	4.48324	109.01
1930	BIL PROC,EX ONLY CHLCYST WO CDE WO CC	1,769	26,208	19,482	1.14513	74.34
1931	BIL PROC,EX ONLY CHLCYST WO CDE W CC	4,828	39,721	30,158	1.73554	75.92
1932	BIL PROC,EX ONLY CHLCYST WO CDE W MCC	2,249	74,646	66,981	3.26155	89.73
1970	CHOLECYSTECTOMY, EX LAPSCPC WO CDE WO CC	6,183	19,471	13,785	0.85074	70.80
1971	CHOLECYSTECTOMY, EX LAPSCPC WO CDE W CC	10,467	31,599	27,013	1.38068	85.49
1972	CHOLECYSTECTOMY, EX LAPSCPC WO CDE W MCC	4,892	60,428	56,554	2.64031	93.59
1990	HEPATOBIL DIAGNOSTIC PROCEDURE WO CC	404	19,401	15,024	0.84768	77.44
1991	HEPATOBIL DIAGNOSTIC PROCEDURE W CC	1,344	31,820	28,907	1.39033	90.85
1992	HEPATOBIL DIAGNOSTIC PROCEDURE W MCC	542	73,071	71,992	3.19273	98.52
2010	OTH HEPATOBIL, PANCREAS O.R. PROC WO CC	139	25,131	22,633	1.09807	90.06
2012	OTH HEPATOBIL, PANCREAS O.R. PROC W MCC	1,134	82,973	91,841	3.62542	110.69
2013	OTH HEPATOBIL, PANCREAS O.R. PROC W CC OR MCC	1,346	41,989	39,661	1.83465	94.46
2030	MALGNCY HEPATOBIL SYS OR PANCREAS WO CC	5,463	15,046	13,224	0.65743	87.89
2031	MALGNCY HEPATOBIL SYS OR PANCREAS W CC	19,007	19,883	19,512	0.86874	98.14

SUMMARY STATISTICS FOR MEDICARE MODIFIED APS-DRGS

MM APS-DRG	Medicare Modified APS-DRG Description	No. of Cases	Mean Std. Total Charge	Stdev. Std. Total Charge	Weight	CV
2032	MALGNCY HEPATOBIL SYS OR PANCREAS W MCC	6,663	30,109	33,261	1.31558	110.47
2040	DISOR OF PANCREAS EX MALIGNANCY WO CC	22,774	11,488	10,280	0.50195	89.48
2041	DISOR OF PANCREAS EX MALIGNANCY W CC	37,482	16,146	16,033	0.70548	99.30
2042	DISOR OF PANCREAS EX MALIGNANCY W MCC	11,464	34,044	41,955	1.48751	123.24
2050	DISORDERS OF LIVER, EX MALIGNANCY WO CC	3,844	11,671	11,970	0.50995	102.56
2051	DISORDERS OF LIVER, EX MALIGNANCY W CC	40,246	15,383	15,862	0.67216	103.11
2052	DISORDERS OF LIVER, EX MALIGNANCY W MCC	15,955	31,295	41,538	1.36739	132.73
2070	DISORDERS OF THE BILIARY TRACT WO CC	14,043	11,342	9,350	0.49556	82.44
2071	DISORDERS OF THE BILIARY TRACT W CC	24,649	16,192	14,725	0.70749	90.94
2072	DISORDERS OF THE BILIARY TRACT W MCC	6,148	29,726	33,482	1.29885	112.63
2100	HIP&FEMUR PROC,EX MAJ JNT WO CC	38,217	20,319	11,650	0.88781	57.34
2101	HIP&FEMUR PROC,EX MAJ JNT W CC	94,713	25,427	16,414	1.11100	64.55
2102	HIP&FEMUR PROC,EX MAJ JNT W MCC	20,123	44,546	41,770	1.94640	93.77
2130	AMPUT MUSC SYST & CONN TISS DISOR WO CC	1,575	15,435	13,289	0.67440	86.10
2131	AMPUT MUSC SYST & CONN TISS DISOR W CC	5,995	25,540	25,049	1.11594	98.08
2132	AMPUT MUSC SYST & CONN TISS DISOR W MCC	2,528	47,666	51,629	2.08268	108.31
2160	BIOPSIES OF MUSC SYST & CONN TISS WO CC	7,381	21,953	13,432	0.95921	61.18
2161	BIOPSIES OF MUSC SYST & CONN TISS W CC	8,618	31,023	23,827	1.35550	76.80
2162	BIOPSIES OF MUSC SYST & CONN TISS W MCC	1,588	54,004	58,927	2.35965	109.12
2170	WND DBRD,SK GRF EX HAND,MUSC,CONN WO CC	2,682	23,104	23,463	1.00951	101.55
2171	WND DBRD,SK GRF EX HAND,MUSC,CONN W CC	8,629	36,183	38,844	1.58098	107.35
2172	WND DBRD,SK GRF EX HAND,MUSC,CONN W MCC	5,989	66,630	81,467	2.91133	122.27
2180	LW EXT&HUM PROC,EX HIP,FT,FEM WO CC	25,074	16,705	10,869	0.72991	65.06
2181	LW EXT&HUM PROC,EX HIP,FT,FEM W CC	21,443	23,697	18,074	1.03540	76.27
2182	LW EXT&HUM PROC,EX HIP,FT,FEM W MCC	3,029	44,556	45,091	1.94683	101.20
2230	SHOULDER,ELBOW,FOREARM PROCEDURES WO CC	15,883	13,249	8,528	0.57892	64.36
2231	SHOULDER,ELBOW,FOREARM PROCEDURES W CC	7,653	17,849	14,250	0.77990	79.83
2232	SHOULDER,ELBOW,FOREARM PROCEDURES W MCC	708	35,090	32,745	1.53319	93.32
2250	FOOT PROCEDURES WO CC	2,678	13,578	9,051	0.59327	66.66
2251	FOOT PROCEDURES W CC	3,345	20,673	21,770	0.90327	105.31

MEAN STANDARDIZED TOTAL CHARGE AND BASE WEIGHTS FOR MEDICARE MODIFIED APS-DRGS

CDRG	Description	MDC	Med-Surg Flag	No CC or No Split			CC or CC/MCC			Major CC		
				No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight
001	CRANIOTOMY	01	S	12,566	31,249	1.33837	8,259	38,090	1.63139	741	49,777	2.13194
006	CARPAL TUNNEL RELEASE	01	S	253	10,482	0.44893	95	13,995	0.59939	2	35,298	1.51182
007	PERIPH&CRAN NERV&OTH NRV SYS PROC	01	S	4,726	27,459	1.17607	4,085	29,651	1.26996	284	36,753	1.57410
009	SPINAL DISORDERS & INJURIES	01	M	609	13,365	0.57244	473	17,764	0.76082	33	21,327	0.91343
010	NERVOUS SYSTEM NEOPLASMS	01	M	5,017	13,878	0.59437	6,442	15,180	0.65014	432	16,281	0.69730
012	DEGENERATIVE NERV SYS DISORDERS	01	M	21,846	10,782	0.46181	15,562	12,225	0.52360	1,284	15,512	0.66436
013	MULTIPLE SCLEROSIS& CEREB ATAXIA	01	M	3,408	10,379	0.44451	2,036	12,952	0.55473	91	13,141	0.56281
014	INTRACRAN HEM OR CEREBRAL INFARCT	01	M	87,902	13,972	0.59840	58,320	16,345	0.70004	7,179	19,425	0.83196
015	NONSPEC CVA & PREC OCC WO INFARCT	01	M	32,144	11,632	0.49819	20,803	13,221	0.56625	1,430	16,482	0.70590
016	NONSPEC CEREBROVASC DISORD	01	M	4,449	11,696	0.50093	4,719	14,289	0.61198	374	18,516	0.79303
018	CRANIAL & PERIPH NERVE DISORDERS	01	M	12,213	11,242	0.48149	12,357	12,560	0.53793	539	14,973	0.64128
020	NERV SYS INF EXC VIRAL MENINGITIS	01	M	1,323	25,479	1.09126	1,241	28,927	1.23893	175	32,182	1.37834
021	VIRAL MENINGITIS	01	M	835	13,872	0.59415	522	19,381	0.83009	66	23,015	0.98573
022	HYPERTENSIVE ENCEPHALOPATHY	01	M	893	10,745	0.46020	860	13,131	0.56240	72	14,398	0.61664
023	NONTRAUMATIC STUPOR & COMA	01	M	2,917	9,513	0.40745	3,059	10,549	0.45181	197	12,915	0.55316
024	SEIZURE & HEADACHE	01	M	35,195	9,957	0.42644	25,837	11,601	0.49687	2,316	15,899	0.68096
027	TRAUM STUPOR & COMA,COMA >1 HR	01	M	2,000	13,440	0.57564	1,242	16,871	0.72257	225	18,411	0.78853
028	TRAUM STUPOR&COMA,COMA<1HR	01	M	8,634	11,859	0.50793	6,470	15,335	0.65678	507	19,767	0.84662
031	CONCUSSION	01	M	2,920	10,381	0.44460	2,171	12,296	0.52665	109	17,341	0.74272
034	OTHER DISORDERS OF NERVOUS SYSTEM	01	M	10,445	10,132	0.43395	10,091	11,816	0.50606	761	14,408	0.61711
037	ORBITAL PROCEDURES	02	S	563	13,376	0.57288	314	16,447	0.70442	13	20,242	0.86698
039	PRIMARY IRIS & LENS PROCEDURES	02	S	242	9,319	0.39915	140	10,494	0.44943			
040	EXTRAOCLR PROCS EXC ORBIT	02	S	803	13,964	0.59805	335	14,870	0.63689			
042	INTRAOCULAR PROCS EXC IRIS & LENS	02	S	1,473	10,402	0.44553	629	12,708	0.54429			
044	ACUTE MAJOR EYE INFECTIONS	02	M	552	8,143	0.34875	346	10,481	0.44889	10	19,898	0.85221
045	NEUROLOGICAL EYE DISORDERS	02	M	1,640	10,471	0.44846	739	12,110	0.51865			
046	OTHER DISORDERS OF EYE	02	M	1,878	8,731	0.37394	1,804	9,974	0.42718	68	15,049	0.64454
049	MAJOR HEAD & NECK PROCEDURES	03	S	937	21,372	0.91536	784	21,466	0.91939	20	41,102	1.76040
051	SALIVARY GLAND PROCEDURES	03	S	1,598	12,015	0.51460	486	14,211	0.60865	4	42,075	1.80205
052	CLEFT LIP & PALATE REPAIR	03	S	235	11,154	0.47774	62	14,439	0.61843	2	57,722	2.47221
053	SINUS & MASTOID PROCS	03	S	1,184	14,563	0.62374	537	19,453	0.83317	40	27,767	1.18926
056	MISC EAR,NOSE,MOUTH& THROAT PROCS	03	S	1,578	11,034	0.47258	6,666	13,398	0.57383	32	21,150	0.90586
061	MYRINGOTOMY W TUBE INSERT	03	S	92	12,280	0.52594	64	18,733	0.80233			
063	OTH EAR,NOSE,MOUTH,THROAT O.R.	03	S	1,245	16,419	0.70320	743	18,681	0.80012	38	24,424	1.04606
064	EAR,NOSE,MOUTH,THROAT MALIGNANCY	03	M	721	10,902	0.46691	823	13,979	0.59870	62	16,688	0.71475
065	DYSEQUILIBRIUM	03	M	25,377	8,726	0.37372	10,175	9,911	0.42450	308	11,776	0.50435
066	EPISTAXIS & EPIGLOTTITIS	03	M	3,149	7,084	0.30340	2,476	8,325	0.35657	78	15,497	0.66374
068	OTITIS MEDIA & URI	03	M	8,429	7,624	0.32655	7,478	9,110	0.39020	337	11,313	0.48453
073	OTH EAR,NOSE,MOUTH,THROAT	03	M	3,543	9,416	0.40330	2,889	11,258	0.48219	224	12,435	0.53258
075	MAJOR CHEST PROCEDURES	04	S	9,115	26,645	1.14119	10,630	31,705	1.35790	606	42,999	1.84162
076	OTHER RESP SYSTEM O.R. PROCEDURES	04	S	3,714	20,212	0.86567	8,211	24,780	1.06131	946	27,950	1.19707
078	PULMONARY EMBOLISM	04	M	7,972	14,294	0.61220	11,672	16,002	0.68535	870	17,146	0.73434

MEAN STANDARDIZED TOTAL CHARGE AND BASE WEIGHTS FOR MEDICARE MODIFIED APS-DRGS

CDRG	Description	MDC	Med-Surg Flag	No CC or No Split			CC or CC/MCC			Major CC		
				No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight
079	RESP INFECT & INFLAM	04	M	14,782	14,537	0.62260	35,309	16,703	0.71541	4,056	18,385	0.78743
082	RESPIRATORY NEOPLASMS	04	M	5,373	13,420	0.57476	11,549	15,677	0.67143	1,157	17,742	0.75989
083	MAJOR CHEST TRAUMA	04	M	2,050	9,676	0.41442	2,649	11,205	0.47993	120	13,143	0.56291
087	PULMONARY EDEMA & RESP FAILURE	04	M	1,658	11,815	0.50602	14,745	14,432	0.61813			
088	CHRONIC OBSTR PULMONARY DISEASE	04	M	167,291	10,876	0.46580	112,381	12,822	0.54915	16,710	14,225	0.60924
089	SIMP PNEU,PLRSY,INSTIT DIS	04	M	84,127	10,255	0.43922	189,816	12,276	0.52578	6,556	14,312	0.61299
094	PNEUMOTHORAX & PLEURAL EFFUSION	04	M	5,926	10,938	0.46848	10,893	13,460	0.57647	926	16,313	0.69870
096	BRONCHITIS & ASTHMA	04	M	36,143	8,631	0.36965	26,984	10,209	0.43727	2,227	11,070	0.47414
099	RESPIRATORY SIGNS & SYMPTOMS	04	M	9,791	8,712	0.37313	8,999	9,749	0.41754	419	11,377	0.48728
101	OTHER RESP SYSTEM DIAGNOSES	04	M	7,221	8,939	0.38286	8,808	10,636	0.45553	666	12,382	0.53033
103	HEART TRANSPL OR IMPL HEART ASST	00	S	24	144,342	6.18211	55	159,830	6.84548			
104	CARD VALV OTH MAJ CARD PR W CATH	05	S	2,321	81,879	3.50686	3,165	89,201	3.82045	197	101,824	4.36110
105	CARD VALV OTH MAJ CARD PR WO CATH	05	S	5,796	65,001	2.78398	6,382	69,463	2.97510	268	87,425	3.74439
106	CORONARY BYPASS WITH PTCA	05	S	622	81,583	3.49417	599	90,823	3.88993	77	96,356	4.12690
108	OTHER CARDIOTHORACIC PROCEDURES	05	S	1,636	58,186	2.49208	1,491	67,445	2.88865	116	76,169	3.26230
110	MAJOR CARDIOVASCULAR PROCS	05	S	14,105	39,373	1.68632	15,377	41,913	1.79513	905	49,052	2.10089
113	AMPUT CIRC DISOR EXC UP LIMB,TOE	05	S	2,485	19,972	0.85541	5,416	23,956	1.02602	372	25,815	1.10563
114	UPPR LIMB,TOE AMPUT CIRC DISOR	05	S	538	13,618	0.58326	1,719	16,105	0.68976	30	22,794	0.97628
117	CARD PACEMKR REVIS EX DEVICE REPL	05	S	1,902	13,094	0.56080	1,392	16,167	0.69241	58	21,601	0.92516
118	CARDIAC PACEMAKER DEVICE REPLACE	05	S	3,352	21,752	0.93162	2,226	25,199	1.07926	37	34,612	1.48241
120	OTHER CIRCULATORY SYST O.R. PROCS	05	S	1,816	18,695	0.80072	8,194	19,652	0.84171	264	27,421	1.17444
121	CIRC DISOR W AMI DISCH ALIVE	05	M	46,611	13,487	0.57765	47,205	15,549	0.66597	3,950	19,108	0.81838
123	CIRC DISOR W AMI, EXPIRED	05	M	1,452	10,146	0.43456	3,197	11,121	0.47629	644	12,842	0.55000
124	CIRC DIS EX AMI W CATH & COMP DX	05	M	63,947	17,756	0.76049	35,028	21,110	0.90415	2,330	28,414	1.21695
125	CIRC DIS EX AMI W CATH WO COMP DX	05	M	61,439	15,653	0.67041	23,703	17,783	0.76164	806	22,419	0.96018
126	ACUTE & SUBACUTE ENDOCARDITIS	05	M	408	19,488	0.83467	548	24,231	1.03782	134	28,788	1.23299
127	HEART FAILURE & SHOCK	05	M	148,691	10,551	0.45190	195,806	12,407	0.53140	15,126	15,182	0.65024
128	DEEP VEIN THROMBOPHLEBITIS	05	M	2,168	8,184	0.35051	1,458	10,017	0.42904	83	12,266	0.52534
129	CARDIAC ARREST, UNEXPLAINED	05	M	407	7,204	0.30854	380	8,275	0.35441	178	11,203	0.47981
130	PERIPHERAL VASCULAR DISORDERS	05	M	30,662	9,074	0.38862	32,804	11,072	0.47423	1,770	13,017	0.55752
132	ATHEROSCLEROSIS	05	M	54,591	8,131	0.34826	36,673	9,314	0.39893	855	12,948	0.55454
134	HYPERTENSION	05	M	23,955	8,192	0.35084	11,122	9,547	0.40891	528	13,670	0.58549
135	CARD CONGEN & VALV DISOR	05	M	2,193	9,780	0.41889	2,574	10,858	0.46503	106	13,284	0.56893
138	CARD ARRHYTHMIA & CONDUCTN DISOR	05	M	110,509	8,605	0.36855	83,491	10,500	0.44970	3,123	13,678	0.58583
140	ANGINA PECTORIS	05	M	20,571	7,064	0.30256	10,282	7,931	0.33969	245	9,362	0.40096
141	SYNCOPE & COLLAPSE	05	M	77,989	9,565	0.40967	51,893	11,044	0.47299	1,983	12,509	0.53574
143	CHEST PAIN	05	M	137,596	8,080	0.34608	65,360	9,119	0.39054	1,427	10,912	0.46735
144	OTH CIRCULATORY SYSTEM DIAGNOSES	05	M	11,748	9,496	0.40669	21,534	11,412	0.48876	1,388	15,209	0.65141
148	MAJOR SMALL & LARGE BOWEL PROCS	06	S	31,202	24,017	1.02866	34,048	29,605	1.26799	3,178	35,362	1.51453
150	PERITONEAL ADHESIOLYSIS	06	S	7,114	21,580	0.92426	6,568	27,815	1.19131	490	34,494	1.47737
152	MINOR SMALL & LARGE BOWEL PROCS	06	S	2,721	17,458	0.74772	1,814	21,922	0.93891	87	28,024	1.20028
154	STOMACH,ESOPH & DUOD PROC	06	S	7,935	22,203	0.95097	6,245	31,435	1.34635	723	36,077	1.54519

MEAN STANDARDIZED TOTAL CHARGE AND BASE WEIGHTS FOR MEDICARE MODIFIED APS-DRGS

CDRG	Description	MDC	Med-Surg Flag	No CC or No Split			CC or CC/MCC			Major CC		
				No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight
157	ANAL & STOMAL PROCEDURES	06	S	5,055	10,881	0.46605	3,440	14,521	0.62191	163	21,326	0.91340
159	HERNIA PROC EXC ING,FEMOR	06	S	14,196	13,531	0.57955	8,247	16,258	0.69631	312	21,972	0.94107
161	ING & FEMORAL HERNIA PROC	06	S	7,068	11,302	0.48406	4,500	14,123	0.60487	140	19,522	0.83611
164	APPENDECTOMY W COMPLIC PRINC DX	06	S	3,110	19,399	0.83084	1,895	24,693	1.05758	101	32,834	1.40627
166	APPENDECTOMY WO COMPLIC PRINC DX	06	S	5,402	14,405	0.61698	2,120	17,134	0.73382	99	20,703	0.88669
168	MOUTH PROCEDURES	03	S	974	12,119	0.51905	686	14,754	0.63192	23	31,079	1.33111
170	OTHER DIGESTIVE SYSTEM O.R. PROCS	06	S	2,072	20,235	0.86667	3,048	24,974	1.06962	324	26,716	1.14423
172	DIGESTIVE MALIGNANCY	06	M	4,523	12,940	0.55420	7,971	15,814	0.67732	632	18,122	0.77617
174	G.I. HEMORRHAGE	06	M	82,073	10,557	0.45215	90,754	12,520	0.53622	3,860	15,655	0.67049
176	COMPLICATED PEPTIC ULCER	06	M	4,463	12,466	0.53393	3,860	14,297	0.61233	261	18,502	0.79241
177	UNCOMPLICATED PEPTIC ULCER	06	M	4,662	11,097	0.47528	3,616	12,707	0.54425	130	15,058	0.64491
179	INFLAMMATORY BOWEL DISEASE	06	M	4,357	12,455	0.53346	4,580	14,299	0.61242	282	18,201	0.77956
180	G.I. OBSTRUCTION	06	M	39,709	9,364	0.40106	33,792	11,589	0.49635	2,127	14,151	0.60610
182	ESPHGITIS,GE,MISC DIG DIS	06	M	143,051	9,282	0.39754	114,380	11,025	0.47219	6,066	12,856	0.55062
185	DENTAL & ORAL DISORDERS	03	M	1,974	8,959	0.38372	1,894	11,099	0.47535	61	13,164	0.56381
188	OTHER DIGESTIVE SYSTEM DX	06	M	20,470	10,332	0.44254	28,974	12,317	0.52754	2,777	13,249	0.56746
191	PANCREAS,LIVER & SHUNT PROCEDURES	07	S	1,989	27,689	1.18591	2,417	34,495	1.47740	199	46,094	1.97418
193	BIL PROC,EX ONLY CHLCYST WO CDE	07	S	1,769	26,208	1.12249	2,095	33,246	1.42390	153	36,111	1.54663
197	CHOLECYSTECTOMY, EX LAPSCPC WO CDE	07	S	6,183	19,471	0.83392	4,969	25,379	1.08698	460	29,703	1.27218
199	HEPATOBIL DIAGNOSTIC PROCEDURE	07	S	404	19,401	0.83092	461	22,283	0.95437	40	38,732	1.65887
201	OTH HEPATOBIL, PANCREAS O.R. PROC	07	S	139	25,131	1.07636	281	28,545	1.22258	23	26,068	1.11649
203	MALGNCY HEPATOBIL SYS OR PANCREAS	07	M	5,463	15,046	0.64443	6,789	16,950	0.72598	436	19,782	0.84724
204	DISOR OF PANCREAS EX MALIGNANCY	07	M	22,774	11,488	0.49202	19,035	13,729	0.58801	1,618	16,753	0.71753
205	DISORDERS OF LIVER, EX MALIGNANCY	07	M	3,844	11,671	0.49987	9,261	11,987	0.51340	425	16,099	0.68953
207	DISORDERS OF THE BILIARY TRACT	07	M	14,043	11,342	0.48576	12,866	13,844	0.59292	794	16,576	0.70993
210	HIP&FEMUR PROC,EX MAJ JNT	08	S	38,217	20,319	0.87026	48,423	22,898	0.98072	1,949	28,015	1.19986
213	AMPUT MUSC SYST & CONN TISS DISOR	08	S	1,575	15,435	0.66107	2,022	18,261	0.78209	182	19,749	0.84584
216	BIOPSIES OF MUSC SYST & CONN TISS	08	S	7,381	21,953	0.94024	4,719	26,754	1.14586	120	28,745	1.23114
217	WND DBRD,SK GRF EX HAND,MUSC,CONN	08	S	2,682	23,104	0.98955	2,952	27,854	1.19297	524	30,258	1.29596
218	LW EXT&HUM PROC,EX HIP,FT,FEM	08	S	25,074	16,705	0.71548	13,131	20,769	0.88952	396	25,167	1.07790
223	SHOULDER,ELBOW,FOREARM PROCEDURES	08	S	15,883	13,249	0.56747	5,309	16,103	0.68967	126	19,464	0.83364
225	FOOT PROCEDURES	08	S	2,678	13,578	0.58154	1,526	16,926	0.72494	34	18,663	0.79935
226	SOFT TISSUE PROCEDURES	08	S	5,874	13,445	0.57585	2,886	17,259	0.73922	116	23,890	1.02318
228	HAND & WRIST PROCECURES	08	S	2,478	12,588	0.53912	956	15,752	0.67464	27	21,192	0.90766
230	LOC EXCIS,REMOV INT FIX HIP,FEMUR	08	S	1,105	13,742	0.58856	607	18,558	0.79485	47	19,725	0.84483
232	ARTHROSCOPY	08	S	77	15,412	0.66009	54	20,570	0.88101			
233	OTH MUSCSKL & CONN TISS O.R. PROC	08	S	9,302	19,452	0.83311	6,474	22,808	0.97686	246	27,669	1.18505
235	FRACTURES OF FEMUR	08	M	1,629	7,674	0.32867	1,401	9,600	0.41117	77	12,247	0.52454
236	FRACTURES OF HIP & PELVIS	08	M	15,079	7,803	0.33422	11,949	9,498	0.40679	595	11,704	0.50129
237	SPRN,STRN,DISLOC HIP,PELVIS,THIGH	08	M	1,036	7,693	0.32950	543	9,488	0.40637	14	10,540	0.45143
238	OSTEOMYELITIS	08	M	1,255	12,200	0.52250	1,919	15,418	0.66034	262	16,186	0.69323
239	PATH FX & MUSC & CONN TISS MALIG	08	M	11,894	11,050	0.47328	12,175	13,312	0.57013	529	15,986	0.68469

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CDRG	Description	MDC	Med-Surg Flag	No CC or No Split			CC or CC/MCC			Major CC		
				No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight
240	CONNECTIVE TISSUE DISORDERS	08	M	3,627	10,890	0.46641	4,114	13,215	0.56599	322	19,599	0.83944
242	SEPTIC ARTHRITIS	08	M	748	10,172	0.43565	759	13,414	0.57450			
243	MEDICAL BACK PROBLEMS	08	M	45,049	9,465	0.40537	29,267	11,275	0.48290	983	15,119	0.64755
246	BONE DISEASES & ARTHROPATHIES	08	M	8,504	7,580	0.32463	7,049	9,088	0.38922	336	12,964	0.55526
247	SIGNS&SYMPTOMS MUSCSKL& CONN TISS	08	M	10,739	7,631	0.32682	6,006	9,092	0.38940	209	12,576	0.53861
248	TENDONITIS, MYOSITIS & BURSITIS	08	M	5,098	9,805	0.41996	4,419	11,537	0.49415	332	14,671	0.62834
249	AFTERCARE, MUSCSKL & CONN TISSUE	08	M	7,084	7,862	0.33673	3,268	10,195	0.43665	173	14,917	0.63889
253	FX,SPR,STR,DSL UP EXT,LOW LEG	08	M	16,279	7,642	0.32731	12,939	9,481	0.40605	456	13,787	0.59049
256	OTHER MUSCSKL & CONN TISS DIAG	08	M	2,146	8,754	0.37495	1,903	10,697	0.45816	99	14,963	0.64088
259	MASTECTOMY FOR MALIGNANCY	09	S	17,008	11,204	0.47988	10,002	12,583	0.53891	68	19,970	0.85533
261	BRST PR NON-MAL,EX BIOP&LOC EXCIS	09	S	1,252	14,267	0.61106	305	15,951	0.68319			
262	BRST BIOP& LOC EXCIS FOR NON-MAL	09	S	300	11,525	0.49360	183	13,645	0.58441			
263	SKN GRFT/DEBRID,SKN ULCR,CELLULIT	09	S	4,931	16,158	0.69202	7,481	20,354	0.87177	450	24,410	1.04548
265	SKN GRFT/DEBRD,EX SKN ULCR,CELLUL	09	S	2,777	14,049	0.60172	2,010	18,418	0.78884	57	26,124	1.11889
267	PERIANAL & PILONIDAL PROCEDURES	09	S	134	10,092	0.43223	72	16,542	0.70848			
269	SKIN,SUBCUT TISSUE & BREAST PROC	09	S	3,736	13,401	0.57395	3,829	17,805	0.76260	155	21,484	0.92016
272	MAJOR SKIN DISORDERS	09	M	4,398	9,509	0.40728	8,201	11,346	0.48595	290	14,024	0.60063
274	MALIGNANT BREAST DISORDERS	09	M	325	9,284	0.39763	515	12,333	0.52820			
276	NON-MALIGNANT BREAST DISORDERS	09	M	613	8,138	0.34853	462	9,890	0.42359			
277	CELLULITIS	09	M	43,158	8,794	0.37663	45,944	10,689	0.45782	1,892	13,410	0.57436
280	TRAUMA SKN,SUBCUT TISS & BREAST	09	M	10,265	8,187	0.35065	8,536	9,611	0.41165	313	12,893	0.55222
283	MINOR SKIN DISORDERS	09	M	2,359	7,484	0.32055	2,768	9,025	0.38653	113	10,855	0.46490
285	AMPUT LOW LIMB ENDO,NUTR,METB DIS	10	S	461	16,314	0.69873	1,368	19,820	0.84888	19	24,378	1.04410
286	ADRENAL & PITUITARY PROCEDURES	10	S	1,320	22,156	0.94895	669	27,111	1.16117	24	40,773	1.74629
287	SKN GRFT,DBRD ENDO,NUTR,METB DIS	10	S	1,405	17,558	0.75200						
288	O.R. PROCEDURES FOR OBESITY	10	S	6,056	25,763	1.10342	2,326	27,654	1.18443	154	36,018	1.54265
289	PARATHYROID PROCEDURES	10	S	4,619	11,222	0.48063	1,327	15,591	0.66776	26	30,303	1.29786
290	THYROID & THYROGLOSSAL PROCS	10	S	7,679	11,586	0.49621	2,017	14,913	0.63872	36	24,598	1.05351
292	OTH ENDOCR,NUTRIT,METAB O.R. PROC	10	S	463	20,962	0.89782	1,220	24,837	1.06376	47	33,612	1.43960
295	DIABETES	10	M	30,258	7,822	0.33500	28,514	9,509	0.40728	1,702	12,911	0.55298
296	NUTRIT & MISC METAB DISOR	10	M	66,638	8,239	0.35287	92,964	9,674	0.41432	7,172	11,456	0.49068
300	ENDOCRINE DISORDERS	10	M	6,083	10,476	0.44869	6,992	13,035	0.55828	404	15,636	0.66969
302	KIDNEY TRANSPLANT	11	S	2,611	69,501	2.97671	2,472	73,683	3.15584	156	84,718	3.62847
303	KIDNEY,URETR,MAJ BLADDR FOR NEOPL	11	S	7,816	22,967	0.98367	5,165	26,675	1.14249	310	31,781	1.36116
304	KIDNY,URETR,MAJ BLADDR NONNEO	11	S	3,977	18,914	0.81010	4,089	22,271	0.95385	172	34,655	1.48425
306	PROSTATECTOMY	11	S	3,501	10,888	0.46633	2,364	14,911	0.63863	59	22,516	0.96434
308	MINOR BLADDER PROCEDURES	11	S	4,704	14,610	0.62572	2,525	16,941	0.72559	94	19,871	0.85105
310	TRANSURETHRAL PROCEDURES	11	S	11,772	11,090	0.47496	9,823	14,438	0.61839	227	19,182	0.82156
312	URETHRAL PROCEDURES	11	S	700	10,996	0.47094	627	13,263	0.56806			
315	OTHER KIDNEY & URINARY TRACT PROCS	11	S	10,210	19,704	0.84391	8,076	22,037	0.94385	467	27,635	1.18361
316	ADMIT FOR RENAL DIALYSIS OR FAILURE	11	M	16,242	10,695	0.45806	30,838	12,398	0.53099	1,894	15,033	0.64387
318	KIDNEY & URINARY TRACT NEOPLASMS	11	M	983	10,882	0.46609	1,404	13,054	0.55908	67	16,119	0.69039

MEAN STANDARDIZED TOTAL CHARGE AND BASE WEIGHTS FOR MEDICARE MODIFIED APS-DRGS

CDRG	Description	MDC	Med-Surg Flag	No CC or No Split			CC or CC/MCC			Major CC		
				No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight
320	KIDNEY,URIN TRACT INFECT	11	M	69,792	9,300	0.39832	71,508	10,981	0.47029	8,674	12,658	0.54213
323	URINARY STONES W ESW LITHOTRIPSY	11	M	647	15,683	0.67169	537	17,673	0.75694			
324	URINARY STONES WO ESW LITHOTRIPSY	11	M	6,748	8,245	0.35314	9,118	9,930	0.42528	165	13,079	0.56016
325	KIDNY,URIN TRACT SIGN,SYMP	11	M	4,233	7,337	0.31423	4,122	8,584	0.36764	163	12,346	0.52876
331	OTH KIDNEY & URIN TRACT DX	11	M	8,471	9,752	0.41768	14,102	11,288	0.48346	1,460	12,767	0.54680
334	MAJOR MALE PELVIC PROCEDURES	12	S	13,894	17,455	0.74760	4,948	19,316	0.82730	111	29,579	1.26684
336	TRANSURETHRAL PROSTATECTOMY	12	S	33,079	9,467	0.40546	14,349	11,013	0.47167	284	16,658	0.71346
339	TESTES PROCEDURES	12	S	647	11,659	0.49935	533	15,044	0.64434			
341	PENIS PROCEDURES	12	S	1,924	16,922	0.72475	678	17,305	0.74116			
342	CIRCUMCISION	12	S	268	9,938	0.42562	155	11,738	0.50272			
344	OTH MALE REPRO SYS PROCS MALIG	12	S	1,684	17,715	0.75871	480	16,818	0.72032			
345	OTH MALE REPRO SYS PROCS EX MALIG	12	S	690	10,852	0.46478	316	15,218	0.65177			
346	MALIGNANCY, MALE REPRO SYSTEM	12	M	497	9,550	0.40903	1,032	11,294	0.48373	30	16,603	0.71108
348	BENIGN PROSTATIC HYPERTROPHY	12	M	1,475	8,032	0.34399	1,435	9,506	0.40712	103	12,288	0.52630
352	OTHER MALE REPRODUCTIVE SYSTEM DX	12	M	2,744	8,333	0.35689	2,505	9,904	0.42417	116	12,285	0.52615
353	PELVIC EVISC,RAD HYST & RAD VULV	13	S	1,043	17,081	0.73159	639	21,357	0.91472	16	34,947	1.49677
354	UTER,ADNEX PROC NON-OV/ADNEX MAL	13	S	5,899	14,401	0.61680	2,855	17,447	0.74724	85	22,312	0.95561
356	FEMALE REPRO SYSTEM RECONST PROCS	13	S	18,800	10,892	0.46650	3,602	12,264	0.52528	45	17,737	0.75965
357	UTER&ADNEX PROC FOR OV,ADNEX MAL	13	S	918	18,286	0.78318	865	22,339	0.95678	26	32,041	1.37230
358	UTER&ADNEX PROC FOR NON-MALIG	13	S	32,873	12,572	0.53846	9,947	14,926	0.63925	271	20,783	0.89015
360	VAGINA, CERVIX & VULVA PROCEDURES	13	S	10,606	11,763	0.50381	2,529	13,817	0.59178	48	19,605	0.83968
361	TUBAL INTERRUPTION	13	S	178	14,828	0.63507	49	15,655	0.67048			
363	D&C,CONIZATION&RADIO-IMPLNT,MALIG	13	S	1,116	11,140	0.47714	466	14,464	0.61950	18	23,340	0.99966
364	D&C,CONIZATION EXC FOR MALIGNANCY	13	S	591	9,952	0.42623	376	12,507	0.53567	18	18,125	0.77629
365	OTHER FEMALE REPRO SYST O.R. PROC	13	S	501	15,141	0.64848	283	18,967	0.81233	19	26,982	1.15564
366	MALIGNANCY, FEMALE REPRO SYSTEM	13	M	663	9,489	0.40643	1,212	12,849	0.55033			
368	INFECTIONS, FEMALE REPRO SYSTEM	13	M	880	11,804	0.50555	885	13,844	0.59292	99	17,724	0.75911
369	MENSTRUAL& OTH FEM REPRO SYS DIS	13	M	1,554	7,576	0.32447	1,032	9,143	0.39158	37	11,258	0.48217
370	CESAREAN SECTION	14	S	2,366	9,468	0.40553	1,011	11,336	0.48553	23	12,901	0.55255
372	VAGINAL DELIVERY W COMPLIC DXS	14	M	678	6,683	0.28621	305	7,482	0.32047			
373	VAGINAL DELIVERY WO COMPLIC DXS	14	M	3,834	5,478	0.23463	840	5,639	0.24154			
374	VAGINAL DELIVERY W OR PROC	14	S	102	8,295	0.35527	32	12,639	0.54133			
376	POSTPART&POST ABORT DX WO OR PROC	14	M	136	4,481	0.19190	124	8,069	0.34559			
377	POSTPART&POST ABORT DX W OR PROC	14	S	21	12,395	0.53086	29	21,787	0.93314			
378	ECTOPIC PREGNANCY	14	M	93	9,597	0.41102	58	10,741	0.46002			
381	ABORTN W D&C,ASP CURETT,HYSTEROT	14	S	123	7,489	0.32074	53	8,784	0.37620			
383	OTH ANTEPARTUM DX	14	M	1,420	5,234	0.22416	1,087	6,835	0.29272	43	13,459	0.57645
392	SPLENECTOMY	16	S	577	24,710	1.05831	460	31,686	1.35709	19	42,611	1.82503
394	OTH O.R PROC BLOOD&BLOOD FORM ORG	16	S	828	15,148	0.64878	595	19,234	0.82377	47	26,056	1.11597
395	RED BLOOD CELL DISORDERS	16	M	33,725	9,668	0.41408	31,621	10,869	0.46553	3,198	13,071	0.55982
397	COAGULATION DISORDERS	16	M	4,273	14,260	0.61077	4,524	17,421	0.74612	411	16,159	0.69207
398	RETICULOENDOTHELIAL & IMMUN DISOR	16	M	3,114	11,157	0.47784	5,494	13,324	0.57064	433	17,753	0.76035

MEAN STANDARDIZED TOTAL CHARGE AND BASE WEIGHTS FOR MEDICARE MODIFIED APS-DRGS

CDRG	Description	MDC	Med-Surg Flag	No CC or No Split			CC or CC/MCC			Major CC		
				No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight
401	LYMPHOMA&NONACU LEUK OTH O.R PROC	17	S	1,819	18,951	0.81168	1,797	26,820	1.14869	107	32,817	1.40556
403	LYMPHOMA & NON-ACUTE LEUKEMIA	17	M	5,324	14,746	0.63158	8,237	17,627	0.75496	805	21,160	0.90628
406	MYEL DIS/PRLY DIF NEO&MAJ OR PROC	17	S	776	20,262	0.86782	692	25,954	1.11159	29	33,648	1.44113
408	MYEL DIS,PRLY DIF NEO&OTH OR PROC	17	S	716	17,126	0.73350	525	23,197	0.99353			
409	RADIOTHERAPY	17	M	658	14,101	0.60394	492	16,132	0.69093			
410	CHEMO WO ACUTE LEUKEMIA AS SEC DX	17	M	5,930	13,315	0.57030	11,349	15,965	0.68379	75	16,140	0.69129
412	HISTORY OF MALIGNANCY	17	M	20	6,945	0.29743						
413	OTH MYEL DIS/POORLY DIFF NEOPL DX	17	M	1,037	13,047	0.55879	1,461	14,805	0.63407	137	16,830	0.72084
415	O.R PROC FOR INFECT & PARASIT DIS	18	S	4,157	20,626	0.88341	5,257	24,697	1.05777	1,246	28,055	1.20157
416	SEPTICEMIA	18	M	38,923	14,084	0.60322						
418	POSTOP & POST-TRAUMATIC INFECT	18	M	4,860	10,851	0.46476	8,257	11,672	0.49989	1,159	15,509	0.66425
419	FEVER OF UNKNOWN ORIGIN	18	M	4,995	9,806	0.42000	6,313	11,136	0.47695			
421	VIRAL ILLNESS	18	M	4,571	8,475	0.36297	3,458	9,763	0.41813	166	12,614	0.54027
423	OTH INFECT & PARASIT DIS DIAG	18	M	914	12,359	0.52935	1,256	14,193	0.60790	212	18,525	0.79341
424	O.R PROC W PRINC DX OF MENTAL ILL	19	S	237	20,473	0.87685	268	26,396	1.13053			
425	ACU ADJ REACT & PSYCHSOCIAL DYSF	19	M	6,377	7,908	0.33870	4,115	9,118	0.39052	203	11,749	0.50323
426	DEPRESSIVE NEUROSES	19	M	2,148	6,309	0.27023	1,188	7,445	0.31886			
427	NEUROSES EXCEPT DEPRESSIVE	19	M	820	7,067	0.30268	413	7,973	0.34149			
428	DISOR OF PERSONALTY&IMPULSE CNTRL	19	M	384	8,915	0.38181	209	11,454	0.49056			
429	ORGANIC DISTURB&MENTAL RETARDATN	19	M	10,262	10,134	0.43405	7,557	11,091	0.47503	476	12,676	0.54290
430	PSYCHOSES	19	M	38,753	9,478	0.40593	17,517	10,099	0.43252	293	12,937	0.55407
432	OTHER MENTAL DISORDER DIAGNOSES	19	M	371	8,034	0.34408	196	9,565	0.40965			
433	ALC/DRUG ABUSE, DEPEND, LEFT AMA	20	M	2,947	3,771	0.16151	1,486	4,709	0.20169	30	6,904	0.29568
439	SKIN GRAFTS FOR INJURIES	21	S	684	16,725	0.71631	460	21,676	0.92838			
440	WOUND DEBRIDEMENTS FOR INJURIES	21	S	1,682	15,473	0.66272	1,464	19,591	0.83910	121	27,974	1.19811
441	HAND PROCEDURES FOR INJURIES	21	S	533	11,437	0.48986	148	16,524	0.70770			
442	OTHER O.R PROCEDURES FOR INJURIES	21	S	4,434	16,213	0.69439	4,741	20,174	0.86405	617	25,913	1.10987
444	TRAUMATIC INJURY	21	M	3,203	8,329	0.35673	2,736	9,513	0.40745	122	11,813	0.50596
447	ALLERGIC REACTIONS	21	M	2,932	5,427	0.23242	1,525	7,430	0.31821	146	14,699	0.62954
449	POISON&TOXIC EFFECTS DRUGS	21	M	10,739	6,888	0.29503	12,963	8,197	0.35109	1,178	13,321	0.57052
452	COMPLICATIONS OF TREATMENT	21	M	8,180	8,803	0.37704	9,144	11,014	0.47174	650	13,697	0.58664
454	OTH INJURY,POISON&TOXIC EFFECT DX	21	M	1,473	7,669	0.32845	1,344	9,478	0.40592	95	12,647	0.54165
461	O.R PROC,DX OTH CONTCT W HLTH SRV	23	S	1,189	16,202	0.69394	590	17,702	0.75818	30	27,363	1.17195
462	REHABILITATION	23	M	915	11,930	0.51096	719	14,272	0.61126			
463	SIGNS & SYMPTOMS	23	M	11,974	8,012	0.34313	12,179	9,201	0.39406	645	10,195	0.43664
467	OTH FCTRS INFLUENCING HLTH STATUS	23	M	1,050	6,987	0.29927	729	7,745	0.33170	39	12,090	0.51783
468	EXTENS O.R PROC UNREL TO PRINC DX	00	S	5,436	29,932	1.28197	6,908	36,495	1.56305	696	44,525	1.90697
471	BILAT OR MULT MAJ JOINT, LOW EXTR	08	S	7,331	42,948	1.83944	4,624	45,106	1.93189	125	51,433	2.20286
473	ACU LEUKEM WO MAJ OR PROC	17	M	912	16,505	0.70688	1,852	23,905	1.02384			
475	RESP SYSTEM DX W VENTIL SUPPORT	04	M	1,037	27,614	1.18269	4,726	28,112	1.20402	2,353	31,828	1.36317
476	PROSTATIC O.R PROC UNREL PRINC DX	00	S	564	16,704	0.71542	621	25,938	1.11092	41	36,190	1.55000
477	NON-EXTEN O.R PROC UNREL PRINC DX	00	S	5,952	15,450	0.66173	6,151	20,806	0.89113	395	24,183	1.03573

MEAN STANDARDIZED TOTAL CHARGE AND BASE WEIGHTS FOR MEDICARE MODIFIED APS-DRGS

CDRG	Description	MDC	Med-Surg Flag	No CC or No Split			CC or CC/MCC			Major CC		
				No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight
480	LIVER &/OR INTESTINAL TRANSPL	00	S	177	107,286	4.59504						
481	BONE MARROW TRANSPLANT	00	S	136	56,952	2.43922	306	74,010	3.16981			
482	TRACHMY FACE,MOUTH AND NECK DIAG	00	S	1,075	31,200	1.33629	1,187	33,523	1.43576	83	38,620	1.65410
484	CRANIOTOMY, MULT SIGNIFICNT TRAUMA	24	S	65	55,339	2.37016	86	57,110	2.44602	28	69,816	2.99018
485	LIMB REATT,HIP&FEMUR,MULT SIG TRM	24	S	726	34,968	1.49765	747	35,039	1.50071	73	61,721	2.64348
486	OTH OR PROC FOR MULTI SIGNF TRAUMA	24	S	597	48,015	2.05647	453	53,664	2.29840	132	84,408	3.61515
487	OTHER MULTIPLE SIGNIFICANT TRAUMA	24	M	1,481	18,812	0.80573	1,049	21,616	0.92580	175	34,016	1.45692
488	HIV W EXTENSIVE O.R. PROCEDURE	25	S	110	30,206	1.29373						
489	HIV W MAJOR RELATED CONDITION	25	M	2,042	14,684	0.62889	2,705	18,436	0.78962	250	23,479	1.00560
490	HIV W OR WO OTH RELATED CONDITION	25	M	892	10,469	0.44840	1,229	12,668	0.54255	78	16,070	0.68825
491	MAJ JOINT/LIMB REATTACH,UPP EXTR	08	S	12,489	23,773	1.01818	4,314	26,765	1.14632	75	36,364	1.55746
492	CHEMO W ACU LEUK SDX,HI DOSE CHEMO	17	M	1,164	18,801	0.80523	899	37,759	1.61721	34	51,860	2.22115
493	LAPAROSCOPIC CHOLECYSTECT WO CDE	07	S	32,874	16,818	0.72031	23,982	21,639	0.92679	1,006	25,859	1.10751
495	LUNG TRANSPLANT	00	S	49	101,863	4.36277	65	118,917	5.09317			
496	COMB ANT/POST SPINAL FUSION	08	S	1,137	72,315	3.09724	765	84,882	3.63547	49	114,455	4.90207
497	SPINAL FUSION EXCEPT CERVICAL	08	S	23,002	43,685	1.87101	13,182	49,467	2.11866	310	59,781	2.56040
499	BACK& NECK PROC EXC SPINAL FUSION	08	S	56,069	14,621	0.62620	18,015	18,690	0.80049	382	27,682	1.18562
501	KNEE PROC W PDX OF INFECTION	08	S	871	22,158	0.94902	1,015	27,840	1.19237	99	31,744	1.35960
503	KNEE PROCS WO PDX OF INFECTION	08	S	3,607	16,052	0.68750	1,365	19,224	0.82337	44	32,746	1.40248
505	EXT,FULL BURN W MV 96+H WO SK GRFT	22	M	64	12,736	0.54549	36	15,692	0.67210			
506	OTHER BURNS W OR PROC	22	S	18	60,956	2.61071	21	143,357	6.13993			
507	FULL BRN W GR OR INHAL WO SIG TR	22	S	366	29,307	1.25521	365	36,587	1.56699	14	59,873	2.56435
510	OTHER BURNS WO OR PROC	22	M	202	13,207	0.56564	249	13,889	0.59485	9	38,057	1.62998
511	NON-EXT BURNS WO SIG TRAUMA	22	M	714	12,018	0.51473	704	12,511	0.53586	23	32,160	1.37740
512	SIMULT PANCREAS/KIDNEY TRANSPLANT	00	S	164	119,264	5.10803	116	123,840	5.30401			
513	PANCREAS TRANSPLANT	00	S	96	77,933	3.33785	50	88,962	3.81020			
515	CARDIAC DEFIBRILLATOR WO CARD CATH	05	S	9,903	76,374	3.27107	13,502	80,149	3.43277	340	80,711	3.45683
518	PERC CV PR WO COR ART STENT OR AMI	05	S	17,817	24,448	1.04710	5,465	26,839	1.14949	120	29,847	1.27836
519	CERVICAL SPINAL FUSION	08	S	16,877	26,371	1.12946	6,093	31,941	1.36804	185	43,811	1.87642
522	ALC/DRUG ABUSE OR DEPEND W REHAB	20	M	5,792	7,283	0.31193	3,354	7,833	0.33547	34	10,806	0.46282
523	ALC/DRUG ABUSE OR DEPEND WO REHAB	20	M	17,395	6,404	0.27430	12,962	8,401	0.35979	429	12,472	0.53416
524	TRANSIENT ISCHEMIA	01	M	61,727	10,201	0.43690	32,339	11,397	0.48814	1,397	13,251	0.56755
525	OTHER HEART ASSIST SYSTEM IMPLANT	05	S	38	93,372	3.99909						
528	INTRACRAN VASC PROCS W PDX HEMORR	01	S	233	64,199	2.74963	265	80,355	3.44159	43	87,783	3.75974
529	VENTRICULAR SHUNT PROCEDURES	01	S	2,688	19,225	0.82338	1,776	24,340	1.04246	85	32,774	1.40369
531	SPINAL PROCEDURES	01	S	2,933	22,853	0.97881	1,862	30,165	1.29194	93	32,400	1.38767
533	EXTRACRANIAL PROCEDURES	01	S	54,081	16,447	0.70440	24,261	19,986	0.85599	672	32,547	1.39397
535	CARD DEFIB W CATH W AMI/HF/SHOCK	05	S	1,799	105,420	4.51510						
536	CARD DEFIB W CATH WO AMI/HF/SHOCK	05	S	3,278	95,904	4.10755						
537	LOC EXC,REM INT FIX DEV EX HIP,FEM	08	S	6,362	15,835	0.67823	3,567	20,451	0.87591	234	25,720	1.10158
539	LYMPHOMA & LEUKEMIA W MAJ O.R PROC	17	S	1,913	19,483	0.83446	1,621	26,956	1.15453	72	45,802	1.96169
541	ECMO,TRCH MV96+/PDX EX FMN W MJ OR	00	S	485	100,899	4.32148						

MEAN STANDARDIZED TOTAL CHARGE AND BASE WEIGHTS FOR MEDICARE MODIFIED APS-DRGS

CDRG	Description	MDC	Med-Surg Flag	No CC or No Split			CC or CC/MCC			Major CC		
				No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight	No. of Cases	Mean Std. Total Charge	Weight
542	TRACH MV96+/PDX EX FMN WO MAJ OR	00	S	821	72,210	3.09274						
543	CRANIOT IMP CHEMO OR CMPLX CNS PDX	01	S	760	40,050	1.71534	933	47,613	2.03923	236	48,618	2.08230
544	MAJ JNT REPL OR REATTACH LOWER EXT	08	S	214,364	27,436	1.17510	108,705	29,217	1.25136	2,862	34,692	1.48583
545	REVISION HIP OR KNEE REPLACEMENT	08	S	19,900	31,743	1.35954	11,325	36,215	1.55109	324	43,387	1.85827
546	SPNL FUSN EX CERV W CRV SPINE, MAL	08	S	562	60,505	2.59140	626	68,791	2.94629			
547	CORONARY BYP W CATH W MAJ CV DX	05	S	8,278	69,183	2.96309	7,607	76,186	3.26303	699	87,420	3.74418
548	CORONARY BYP W CATH WO MAJ CV DX	05	S	13,597	62,806	2.68994	9,045	67,855	2.90620	434	78,917	3.38000
549	CORONARY BYP WO CATH W MAJ CV DX	05	S	3,187	55,459	2.37530	3,220	61,042	2.61440	233	77,052	3.30013
550	CORONARY BYP WO CATH WO MAJ CV DX	05	S	15,344	48,962	2.09701	9,588	52,514	2.24918	435	56,963	2.43972
551	PERM PMKR W MJ CV DX,AICD LD,GNRTR	05	S	17,332	39,266	1.68177	16,309	43,878	1.87927	867	48,194	2.06414
552	OTH PERM PMKR IMPL WO MAJ CV DX	05	S	51,379	30,052	1.28711	20,406	34,072	1.45929	668	39,787	1.70407
553	OTHER VASCULAR PROCS W MAJ CV DX	05	S	5,772	28,732	1.23057	8,213	31,549	1.35123	408	43,265	1.85302
554	OTHER VASCULAR PROCS WO MAJ CV DX	05	S	31,639	23,217	0.99438	33,360	26,120	1.11873	623	31,100	1.33199
555	PERC CV PROC W MAJOR CV DX	05	S	34,469	31,935	1.36778	18,006	34,572	1.48073	1,165	44,879	1.92216
556	PRC CV PR W NDRG STENT WO MJ CV DX	05	S	35,390	28,294	1.21184	10,092	30,516	1.30698	248	39,495	1.69158
557	PRC CV PR W DRUG STENT W MJ CV DX	05	S	49,297	39,315	1.68383	23,427	43,318	1.85531	1,340	54,508	2.33455
558	PRC CV PR W DRUG STENT WO MJ CV DX	05	S	114,254	33,423	1.43149	28,414	36,056	1.54425	584	43,411	1.85928
559	AC ISCH STROKE W THROMBOLYTC AGENT	01	M	800	26,474	1.13385	488	30,542	1.30810	86	39,781	1.70380

ESTIMATED CASE-SPECIFIC WEIGHT ADJUSTMENT FACTORS FOR MM APS-DRGS

MDC	Description	Medical Discharges		Surgical Discharges	
		CCs	Major CCs	CCs	Major CCs
00	Cases Grouped Prior to MDC Processing	n.a.	n.a.	0.25113	0.53899
01	Diseases and Disorders of the Nervous System	0.22802	0.87661	0.22101	0.59951
02	Diseases and Disorders of the Eye	0.22337	1.50264	0.34147	1.35971
03	Diseases and Disorders of the Ear, Nose, Mouth and Throat	0.25166	1.07364	0.25515	0.74519
04	Diseases and Disorders of the Respiratory System	0.23345	0.38356	0.24162	0.87780
05	Diseases and Disorders of the Circulatory System	0.23726	0.89087	0.19332	0.54910
06	Diseases and Disorders of the Digestive System	0.25891	1.12530	0.27284	0.72292
07	Diseases and Disorders of the Hepatobiliary System and Pancreas	0.20437	1.02023	0.25820	0.86390
08	Diseases and Disorders of the Musculoskeletal System and Connective Tissue	0.25369	1.20653	0.18402	0.72535
09	Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast	0.25042	1.25532	0.33352	1.24594
10	Endocrine, Nutritional and Metabolic Diseases and Disorders	0.26334	1.14554	0.29164	0.97118
11	Diseases and Disorders of the Kidney and Urinary System	0.25610	0.98662	0.29817	0.96109
12	Diseases and Disorders of the Male Reproductive System	0.21117	0.84127	0.34238	1.28314
13	Diseases and Disorders of the Female Reproductive System	0.27538	0.99808	0.28126	0.99193
14	Pregnancy, Childbirth and the Puerperium	0.36170	2.28574	0.41504	1.54396
15	Newborns and Other Neonates	0.00000	0.00000	0.00000	0.00000
16	Diseases and Disorders of the Blood and Blood-Forming Organs and Immunological Disorders	0.24436	1.24081	0.28030	0.74961
17	Myeloproliferative Diseases and Disorders and Poorly Differentiated Neoplasms	0.33928	1.02881	0.33811	0.86925
18	Infectious and Parasitic Diseases (Systemic or Unspecified Sites)	0.28037	0.88532	0.34050	0.91021
19	Mental Diseases and Disorders	0.21530	1.04370	0.36132	1.02167
20	Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders	0.26881	1.59047	n.a.	n.a.
21	Injuries, Poisonings and Toxic Effects of Drugs	0.27961	1.19116	0.34909	1.28715
22	Burns	0.17717	1.57233	0.31010	0.12276
23	Factors Influencing Health Status and Other Contacts with Health Services	0.22709	1.41451	0.25100	0.97226
24	Mutiple Significant Trauma	0.17378	0.47688	0.07958	0.30614
25	HIV Infection	0.29443	0.88337	0.38781	0.76080

Appendix VIII.
Estimation Procedures

Under the Ingenix proposal, the relative weight assigned to an individual case is based on three statistically estimated parameters:

- A baseline weight corresponding to the APS-DRG terminal category to which the case is assigned
- An adjustment factor ($\beta 1$) that measures the percentage change in the baseline weight attributable to each independent coexisting clinical condition (CC) on the case that is not used for assigning the case to a terminal category, and
- An adjustment factor ($\beta 2$) that measures the percentage change in the baseline weight attributable to each independent major coexisting clinical condition (MCC) on the case that is not used for assigning the case to a terminal category.

The simplest approach to estimating these parameters is to separate the estimation process into three stages: (1) first estimate the baseline expected values (2) estimate the adjustment factors that correspond to $\beta 1$ and $\beta 2$, and (3) normalize the baseline expected values to produce a final set of baseline weights. One option for the first stage is to restrict the analysis to cases that have no CCs or MCCs other than those used to assign the case to a terminal category. Using this subset of claims, it is then straightforward to calculate the expected values by terminal category. In the second stage, these baseline expected values are merged back onto the entire analytic file without regard to the number of CCs and MCCs. If we assume for expositional purposes that the outcome of interest is the cost of a case, the second stage then requires that actual costs be transformed into a percentage deviation of actual cost from expected cost for each case:

Percent Deviation = (Actual Cost)/(Expected Cost) -1

where expected costs are actually the baseline expected values calculated in the first stage. The CC and MCC adjustment factors described above can then be obtained by regressing the count variables, NCC_i and $NMCC_i$, on the Percent Deviation of actual from expected cost:

$$PD_i = \beta 1 \times NCC_i + \beta 2 \times NMCC_i + \text{error}$$

where PD_i indicates the percent deviation of actual from expected costs. This regression can be run in the aggregate or for specific subsets of data, as appropriate. Ingenix proposes to disaggregate the adjustment factors by MDC and medical-surgical status. If we treat all DRGs that are assigned prior to standard MDC processing as their own, separate "pseudo-MDC," our proposal means that there are a total of 26 CC adjustment factors and 26 MCC adjustment factors.

In the third stage, the baseline expected values and estimates for $\beta 1$ and $\beta 2$ are used to construct final, case-specific expected values for each record in the database. Case-specific expected values are then aggregated and compared to aggregate actual costs to produce a suitable normalization factor for converting expected values into weights. Since the model is multiplicative, the normalization process can be viewed as applying

entirely to the baseline expected values. That is, it converts expected baseline values into baseline weights.

Case-specific weights have a number of advantages over the more traditional approach of assigning a single, scalar weight to each terminal category. It explicitly recognizes the incremental costs of care associated with coexisting clinical condition and does so in a simple a straightforward manner. As with other aspects of our proposal, it is a logical extension of current CMS methods and even uses the concept of exclusion logic to identify the *independent* coexisting conditions that are recognized by the model. The specification of the regression is quite flexible and can be used to accommodate any number of factors that may affect severity, e.g., age and source of admission. Our proposal provides a simple and transparent approach to the problem of multiple coexisting clinical conditions and is easy both to estimate and to explain. Finally, and perhaps most importantly, as discussed in the following section, it outperforms Consolidated Severity-adjusted DRGs in explaining case-level variations in resource use.

The estimation procedures described above are not statistically efficient in the sense that they do not utilize all available information to estimate the baseline expected values in Stage 1. One enhancement that might be considered, for example, is to use the adjustment factors from Stage 2 to create an "adjusted actual" value by dividing each actual value (e.g., actual cost) by (β1xNCC+β2xNMCC) for all observations, not just those where NCC=NMCC=0. The "adjusted actuals" can then be used to construct new baseline expected values; the new baseline expected values in turn will yield new estimated adjustment factors; and the entire processes can be iterated to convergence.

This iterative estimation procedure is likely to have the most value in situations where there are a large number of total discharges in a terminal category but relatively few discharges for which NCC=MCC=0. Because there are relatively few sparse cells in the 2004 MedPAR file or in the subset for which NCC=NMCC=0, Ingenix did not use this iterative procedure for the empirical work reported below. That decision should be reconsidered as part of any eventual implementation of APS-DRGs in the Medicare program.

The LEWIN GROUP

An Evaluation of APS-DRGs In Comparison to the Newly Proposed CSA-DRGs

Final Report

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

The fairness and efficiency of Medicare's system of paying acute care hospitals depends, in part, on the system's ability to distinguish cases according to the patient's severity of illness. To better meet this objective, the Centers for Medicare and Medicaid Services (CMS) proposed using consolidated severity-adjusted DRGs (CSA-DRGs) in its Notice of Proposed Rulemaking (NPRM) dated April 25, 2006. Ingenix has developed the Medicare modified all patient-severity DRGs (or "modified APS-DRGs")[1] and proposes that CMS formally consider APS-DRGs as an alternative to the CSA-DRGs. The Lewin Group was engaged by Ingenix to conduct an independent evaluation of its APS-DRG system in comparison to CSA-DRGs.

As part of this evaluation, we reviewed the documentation for the two systems, examined the NPRM and descriptions of earlier systems, and performed a series of comparative regression analyses. Our evaluation was constrained by the extent of the information available on APR-DRG grouping logic and by the inherent time constraints associated with responding to proposed rulemaking.

Primary Assessment

After evaluation, The Lewin Group concluded that Ingenix's modified APS-DRGs are fundamentally simpler and more flexible than CSA-DRGs. Because of this simplicity and flexibility, the modified APS-DRGs may be more transparent, easier for hospitals to implement, and easier to maintain and improve over time than CSA-DRGs. Furthermore, the Lewin Group found that APS-DRGs explain at least as much variance in patient case costs as CSA-DRGs and are less likely to underpay high-casemix hospitals than CSA-DRGs.

APS-DRGs are a hybrid of two analytic systems already in use by CMS:

- Each case is assigned to one and only one cell (i.e. DRG) [2]; and
- Within a cell, a case may involve an add-on payment that reflects the case's greater than average severity. This add-on payment amount is calculated via regression analysis as with CMS' current risk adjustment systems.

APS-DRGs build on CMS' current co-morbidity conditions and complications (CC) listings and exclusion logic but recognize the differences in severity among patients. On the one hand, this represents a paradigm shift in patient categorization methodology for acute care hospital payments - one that better reflects varying levels of severity for inpatients within DRG based cells. On the other hand, CMS currently uses similar systems to pay psychiatric hospitals and managed care organizations.

The goal of CMS in selecting a severity adjusted DRG system is to limit the within-group variation in resource use to improve homogeneity within DRGs, and, at the same time, adequately reflect an individual patient's severity, as CMS has been tasked to do by the

[1] The original APS-DRGs were developed by HHS, Inc. , which was acquired by Ingenix in May 2005. The APS-DRG system has been modified for the Medicare population.
[2] The current DRG system does have an add-on payment for technology but no add-on payment for severity.

Medicare Payment Advisory Commission (MedPAC). The final classification system selected also needs to meet CMS' longstanding goals of administrative feasibility and transparency so that hospitals can fully understand its expectations and rules.

CMS documents and other key literature discuss the following key criteria for evaluating severity-based DRG systems and the extent to which they offer the following features or enhancements to the DRG system without undue implementation burdens (see references).

- Maintaining transparency, administrative ease and public availability;
- Limiting costs of implementation and maintenance;
- Limiting manipulation potential;
- Including clinically meaningful severity assessments; and
- Enhancing ability to systematically predict resource use.

Transparency, Administrative Ease and Public Availability

Transparency is an issue that occurs across many aspects of government and some aspects of business. In a democracy, transparency (i.e., publicly available information) is considered desirable except in special exceptions. For instance, under the Freedom of Information Act (FOIA), citizens can obtain information on a wide range of topics, but not all (e.g., personnel matters). CMS payment policies have generally been transparent.

In the case of DRGs, transparency results in an understanding of the logic of DRG systems, which is important for two reasons:

1. For policy creation, understanding facilitates public discussion; and,
2. For program implementation, understanding facilitates both the initial implementation and long-term maintenance.

Unlike the proposed CSA-DRGs, each component of the modified APS-DRG system can be readily examined. The first part of the hybrid system incorporates the existing CC listings and exclusion logic, which are already publicly available. The second part involves an add-on payment for each additional comorbidity. Understanding the general approach does not require a detailed knowledge of medical conditions and coding. While there undoubtedly are subtleties, analysts will be able to quickly understand the basic logic of this approach.

To date, CMS has not provided adequate documentation (e.g., CC lists and the exclusion logic tables) to allow users to fully understand the CSA-DRG assignment process. This may be, in part, due to the iterative approach taken in refining the system. Because some cases are assigned to a given CSA-DRG, apparently based on different combinations of secondary diagnoses and potential exclusions, one cannot reconstruct (i.e., reverse engineer) the assignment algorithm from the DRG assignment of specific cases. It is our conclusion that the CSA-DRGs are more difficult for potential users to understand than the modified APS-DRGs. Transparency is a critical concern as DRG assignment has become more sophisticated and complex.

A higher degree of transparency will also mean that all the technical aspects of a system (for example, the DRG grouper, assignment of severity, etc.) will be available to the public. This is particularly critical in ensuring CMS can continue to engage in an on-going public dialogue regarding changes in hospital admitting practices, payments, and technology and actively seeks the participation and feedback from hospitals. Being able to readily understand program rules allows coders to more appropriately and efficiently reflect resource utilization in their every day coding and management practices.

Limiting Costs of Implementation and Maintenance

Regardless of the severity system ultimately selected, CMS will incur costs in refining the approach before the issuance of a final rule, throughout implementation, and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community. The CSA-DRG system and its complex algorithms, although based on APR-DRGs which have been carefully conceived over many years of research and development, make it less transparent, flexible or amenable to later refinement and modifications. By forgoing transparency when introducing such new systems, CMS may ultimately increase its implementation and maintenance costs beyond what might be required to implement the modified APS-DRGs.

Manipulation Potential

Another key concern of policymakers, since the inception of the IPPS, has been to limit manipulation potential which any system is vulnerable during implementation. As the DRG system becomes more complex, changes proposed to add a severity of illness adjustment to the system should account for the potential for inappropriate manipulation in reporting, coding, and grouping procedures, as well as assigning diagnoses to improve reimbursement beyond that intended by the system.

Part of the reason CMS has been reluctant to implement a severity refined DRG system is a fear of upcoding and manipulation, as occurred at the inception of the IPPS in 1983. The more transparent the system, the easier the system will be to manipulate, since the results that coding will produce will be clear. However, there is upcoding potential in both proposed systems, and this may be the price to be paid in order to achieve the benefits of more powerful severity measurements. In any event, CMS, as it has in the past, always has the option to disentangle real casemix increases from "DRG creep" by reducing the rate of increase accordingly in the subsequent year. And finally, CMS has exactly the same problem with its capitated risk adjustment system so its adaptive policies will be well formulated.

Clinically Meaningful

Any proposed new approach to recognize severity of illness must also be appropriate and consistent in terms of its clinical approach. The APS-DRG system has structured the clinical knowledge base into its system in a tabular form; conversely, the CSA-DRG system requires multiple decision rules imbedded in computer codes. The modified APS-DRGs use the same basic approach in terms of the first phases of the assignment process where clinical issues are explicitly considered.

Systematically Predicting Treatment Cost

The two casemix systems use approximately the same number of DRGs. However, only the APS-DRG system includes an add-on to the weights (and hence payments) that recognizes the number of independent comorbidities. Because of this second component, we hypothesized that APS-DRGs predict treatment cost (or resource utilization) better than CSA-DRGs. We test this hypothesis as part of our analyses.

The more accurately a casemix system predicts resource use, the better suited it is to support payment. In this context statistical performance has two components: the ability to explain variance (as measured by R-squared) and plausible coefficients. Regarding the latter issue, a ten percent increase, for instance, in casemix across hospitals should be associated with a ten percent increase in cost; that is, cost should have an elasticity of 1.0 with respect to casemix.

To assess these casemix systems, we performed regression analyses using 2004 Medicare MedPAR data. Cost, standardized for payment variables, was regressed on the various casemix measures. [3] From the results, we drew two conclusions. First, modified APS-DRGs explain at least as much variance as CSA-DRGs. Second, costs have elasticity above 1.0 with respect to CSA-DRGs but only slightly above 1.0 for APS-DRGs, so both systems would underpay high-casemix hospitals. However, the problem is substantially less under APS-DRGs.

Conclusion

After a careful assessment, The Lewin Group has concluded that the modified APS-DRGs are worthy of consideration by CMS and the public policy community as an alternative to the proposed CSA-DRGs. The modified APS-DRGs offer a simpler, more transparent, and perhaps more accurate approach by essentially extending CMS' current approach to DRGs and adding the value of risk adjustment type methodologies. CMS already uses this hybrid methodology to pay psychiatric hospitals and managed care organizations. We found that APS-DRGs are statistically sound.

CMS has traditionally made its payment policies transparent. Regardless of what system CMS implements, we urge it continue this tradition by making the grouper logic entirely transparent and publicly available at minimal cost.

[3] In one of its publicly available datasets, CMS has applied the CSA-DRG software to all the discharges in 2004. We had access to this dataset, not to the algorithm.

I. Background and Purpose

On April 25, 2006, the Centers for Medicare & Medicaid Services (CMS) issued proposed changes to the Medicare hospital inpatient prospective payment system (IPPS) based on the recommendations provided by the Medicare Payment Advisory Committee (MedPAC). These recommendations included the addition of severity of illness refinements to current diagnosis related groups (DRGs) and the application of hospital-specific relative value (HSRV) weights to DRGs in order to increase the accuracy of Medicare payments and prevent hospitals from "cherry picking" cases that would be the most profitable.

The proposed consolidated severity-adjusted DRGs (CSA-DRGs) are a version of 3M's current all patient-refined DRGs (APR-DRGs), currently used by the State of Maryland for hospital payment and by a number of other state health information agencies and other organizations for quality monitoring. In the proposed rule, CMS has requested "public comments on whether there are alternative DRG systems that could result in better recognition of severity than the consolidated severity-adjusted DRGs" they are proposing.

The Lewin Group was engaged by Ingenix to conduct an independent evaluation of its proposed alternative to the CSA-DRGs - the modified APS-DRGs. In this paper, we discuss the findings of our evaluation and the methods through which we compared the modified APS-DRGs to the CSA-DRGs. We present evaluation criteria, describe the origins and approach of each system, and describe how the systems compare to each other. We then provide a qualitative and quantitative assessment of the modified APS-DRGs and the unique system they have developed to assign individual patient weights which takes into account both casemix and adds risk adjustments for additional independent co-morbidities. Based on these analyses, we recommend the modified APS-DRG system be seriously considered as an alternative to the CSA-DRGs when CMS replaces the current DRG system with an improved capability to assess patient severity.

II. Systematic Evaluation Criteria

The goal of CMS in selecting any severity adjusted DRG system is to limit the within-group variation in resource use to improve homogeneity within DRGs, and *at the same time adequately reflect an individual patient's severity*, as CMS has been tasked to do by the Medicare Payment Advisory Commission (MedPAC). The final classification system selected also needs to meet CMS' longstanding goals of administrative feasibility and transparency so that hospitals can fully understand its rules and their implications.

CMS documents and other literature discuss the following key criteria for evaluating severity-based DRG systems and the extent to which they offer the following features or enhancements to the DRG system without undue implementation burdens (see references).

- Maintaining transparency, administrative ease and public availability;
- Limiting costs of implementation and maintenance;
- Limiting manipulation potential;

- Including clinically meaningful severity assessments; and
- Enhancing ability to systematically predict resource use.

There have been a number of attempts to enhance existing DRGs ability to more precisely predict resource use by addressing differences in patient severity, to include RDRGs, SDRGs, APR-DRGs, APS-DRGs and now CSA-DRGs and the modified APS-DRGs. Each has taken a slightly different approach to this effort, resulting in different levels of potential system manipulation, system stability and implementation costs. All have involved both a statistical and clinical evaluation of the appropriateness of severity measures in an effort to ensure that the final assignments are reasonable clinically in addition to correlating to case costs (resource utilization). The greatest challenge is to develop a system that meets all of these criteria, but is also simple enough to be understood by the end users, and as transparent as possible to stakeholders with varying degrees of knowledge about patient classification systems. The system should offer administration ease and minimize added costs.

The final system should be able to be explained and understood by those using it in such a way that encourages broad support for system changes or revisions over time. This requires a fair approach that at the same time brings more accuracy to the classification system.

A. *Ensuring Transparency, Administrative Ease and Public Availability*

A critical element to incorporating severity of illness into the DRG system is ensuring that the methodology is both logical and understandable, and relatively transparent to the user. The goal of developing a system that is sophisticated, precise, and addresses as many possible differences in severity is competing with that of choosing a system which is transparent. Nonetheless, the system selected should offer a fair balance between both goals.

Transparency is of particular concern for DRG systems as DRG assignment has become more sophisticated and complex. Transparency has two dimensions:

1. For policy creation, understanding facilitates public discussion; and,
2. For program implementation, understanding facilitates both the initial implementation and long-term maintenance.

The level of transparency affects operational ease in terms of system implementation and maintenance. A higher degree of transparency will also mean that all the technical aspects of a system (for example, the DRG grouper, assignment of severity, etc) will be available to the public. This is particularly critical in ensuring that CMS can continue to engage in an on-going public dialogue regarding changes in hospital admitting practices, payments, and technology and actively seeks the participation and feedback from hospitals. In addition, being able to readily understand program rules allows coders to more appropriately and efficiently reflect resource utilization in their daily coding and management practices.

B. *Limiting Costs of Implementation and Maintenance*

Limiting costs of implementing and maintaining any changes in the DRG system, as well as keeping the impact of the changes budget neutral, remain a high priority.

CMS has already invested in development costs by engaging 3M to assess the potential use of the APR-DRGs in making its severity adjustment system. As described in more detail later in this paper, CMS has identified a way to work with the existing APR-DRGs in a consolidated fashion to adjust for severity of illness in patient DRG assignments.

Alternative proposals should not add significantly to CMS' development costs, or the costs of implementing system changes. A key system limitation which needs to be considered in any proposal needs to be the recognition that the current system can only accommodate three digit DRGs. Any increase in the number of digits required for a DRG classification would result in significant and unmanageable extra system costs at a time of increasing budgetary constraints. Second, the data required to make the severity assessments should not be significantly increased beyond what the hospitals already must identify prior to making a DRG assignment.

Both the CSA-DRGs and the APS-DRGs address these concerns in that they make use of three digit DRGs and do not require hospitals to collect different information than that already required for the current CMS DRGs. With either system, coders are likely to be more alert to properly documenting CCs, and to include secondary CCs, since they will affect the severity classifications.

Regardless of which proposal is ultimately selected, CMS will incur costs in refining the approach both before the issuance of a final rule, throughout implementation and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community.

Because the modified APS-DRGs are an extension of the current system with the addition of a risk adjustment feature, they appear to limit implementation costs and offer greater administrative ease.

C. *Limiting Manipulation Potential*

Since the inception of the IPPS, policymakers have made efforts to limit the manipulation potential which any given approach has upon implementation. As the DRG system becomes more complex, any changes proposed in order to add a severity of illness adjustment to the system need to take into account the potential that such changes might lead to inappropriate manipulation. Manipulation can occur in the reporting, coding and grouping of procedures, as well as the assignment of diagnoses to improve reimbursement beyond that intended by the system.

CMS has been reluctant to implement a severity refined DRG system, in part, due to concerns about upcoding and manipulation, as occurred at inception of PPS in 1983. There is upcoding potential in both proposed systems and a certain amount of this may be unavoidable. In any event, as it has in the past, CMS always has the option to disentangle real casemix increases from "DRG creep" by reducing its rate of increase in payments accordingly in the subsequent year.

While having substantial advantages in the creation and implementation of public policy, transparency probably facilitates the manipulation of codes to increase payment. The argument is straightforward: in any system, the more one knows how inputs affect outcomes, the easier it is to select the inputs that result in the desired outcome. For this reason, APS-DRGs may be more vulnerable to manipulation. However, there is upcoding potential in both proposed systems, and this may be the price to be paid in order to achieve the benefits of more powerful severity measurements. And finally, CMS has exactly the same problem with its capitated risk adjustment system so its adaptive policies will be well formulated.

D. Clinically Meaningful Severity Assessments

Any proposal to recognize severity of illness must also be appropriate and consistent in terms of its clinical approach. The APS-DRG system has structured the clinical knowledge base into its system in a tabular form rather than through multiple series of algorithms imbedded within computer codes. The modified APS-DRGs use the same basic approach in terms of the first phases of the assignment process where clinical issues are considered.

E. Predicting Treatment Costs

In this context statistical performance has two components: the ability to explain variance (as measured by R-squared) and plausible coefficients. Regarding the latter issue, a ten percent increase, say, in casemix across hospitals should be associated with a ten percent increase in costs; that is, cost should be proportionate to casemix. Casemix should have a coefficient (or elasticity) of 1.0.

The following section compares and contrasts how each proposed severity-adjusted DRG system address the evaluation criteria set forth above.

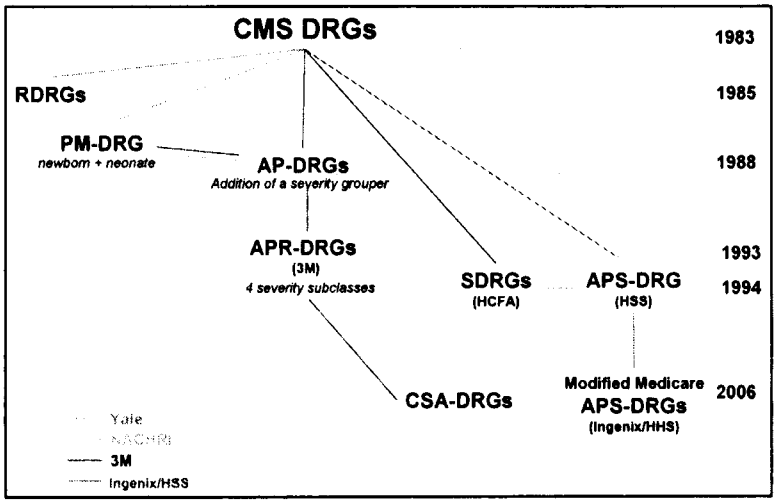
III. ASSESSMENT OF APS-DRGS AND COMPARISON TO CSA-DRGS

A. Development/Evolution of Severity-Adjusted DRGs

The Lewin Group took a number of steps to evaluate the modified APS-DRG system and compare it to the CSA-DRGs. First, we looked at the development of each in a historical context to delineate over several decades of DRG refinements, and the lineage and history of each system. While all DRG patient classification systems are designed to help appropriately predict resource use, each system offers its own combination of enhancements and limitations.

Since the inception of the original DRGs created at Yale University in the late 1960s, and the later adoption of these DRGs by Medicare in 1983, DRG refinements have resulted in a number of different systems and approaches, starting with the development of a prospective payment system to monitor resource utilization. The DRGs have been continually refined to be more useful for all patients beyond the Medicare population (PM-DRGs , AP-DRGs, APR-DRGs and APS-DRGs). ***Figure 1*** illustrates the origin of different DRGs beginning with the Medicare DRGs that were introduced into the IPPS in 1983, which are now moving into their 24th version. The figure provides a snapshot of where we are today as new severity related patient classification systems are being considered and helps to identify the links between current proposals and the systems and refinements which have developed over decades.

Figure 1: The Evolution of DRGs



Of the developers of these systems, 3M has made numerous contributions in the development of DRG technology. Recently, 3M was contracted by CMS to help develop a refined DRG system which incorporates severity measures in keeping with MedPAC's recommendations. This joint effort with CMS has resulted in a consolidated version of 3M's APR-DRG system, referred to as the CSA-DRGs, that is a part of the proposed rulemaking.

According to a Health Care Financing Administration (HCFA) document produced in 1994, the APR-DRGs were developed to address limitations in a set of refined DRGs (RDRGs) that were created by Yale.[4] RDRGs used Medicare DRGs (CMS DRGs) as their base DRGs and consequently had several drawbacks. They did not address the non-Medicare population, did not recognize the impact of multiple co-morbidities and complications (CCs), and the CC subclass was limited to the Medicare list of CCs. In addition, the structure of RDRGs included four surgical subclasses and three medical subclasses that HCFA cited in this report as inconsistent and confusing. As a result, 3M created the APR-DRGs using existing consolidated all-patient DRGs (AP-DRGs)[5] as the initial base APR-DRGs and after "a series of consolidations, additions, and modifications "[6] were made to these initial APR-DRGs, new consolidated base APR-DRGs were created. As a result of the multitude of iterations, APR-DRGs are highly complex and difficult to trace back to the original CMS DRGs. CSA-DRGs are an additional

[4] HCFA. "Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity". June 1994.

[5] AP-DRGs were a joint effort between the New York State Department of Health and 3M in order to create a state prospective payment system for non-Medicare patients and incorporated Pediatric Modified DRGs (PM-DRGs) developed by the National Association of Children's Hospitals and Related Institutions (NACHRI) to include DRG categories for neonatal and pediatric patients.

[6] Averill, et al. "All Patient Refined Diagnosis Related Groups (APR DRGs) Methodology Review version 23.0 . 3M Health Information Systems. 2006.

modification of the consolidated APR-DRGs. In the CSA-DRGs, DRGs not used by the Medicare population have been removed and some additional consolidations were made.

In an effort to address "concerns about the fairness of hospital payment and the ability of the DRG classification to adequately capture differences in levels of patient illness that impact resource consumption" HCFA introduced a new set of DRGs called severity refined DRGs (SDRGs) in 1994. They incorporated severity measures and were also known as severity-refined DRGs. These SDRGs were introduced in a manual which also included an analysis of the DRG systems at that time, particularly RDRGs and AP-DRGs. There was no analysis of the APR-DRGs, since HCFA maintained that the similarity between the APR-DRG and other systems they evaluated would produce similar results.

HCFA concluded for APR-DRGs' that "significant increase in the number of DRG classes and the resulting probability of increased low-volume DRGs and instability in relative weights from one year to the next would offset the systems' significant improvement in case-level homogeneity and ability to explain resource use for severely ill patients. In addition, the relatively complicated algorithm that [was] used [with the APR-DRGs] to determine the complexity subclass of a case is not easily explained or understood. [HCFA] believe[d] this would make it more difficult for a typical hospital to have enough experience to allow meaningful comparative analyses to be performed."[7]

These findings supported HCFA's development of SDRGs "which would incorporate aspects of both the Yale RDRGs and the New York AP-DRGs". However, the SDRGs modified the RDRGs by not automatically creating a major CC class for every DRG and, unlike the AP-DRGs, would not contain major CC DRGs on an MDC level. Instead, SDRGs consider DRGs for groups of patients with major CCs or CCs on a DRG-by-DRG basis. This resulted in a DRG classification system that included a severity measurement based on secondary diagnoses that are classified as major CCs, thereby offering the possibility of "increas[ing] DRG homogeneity, improv[ing] patient equity, and recogniz[ing] the impact of varying severity levels on resource consumption."

Building on this foundation of SDRGs, HSS, now a subsidiary of Ingenix, created an enhanced version of DRGs that considered non-Medicare patient conditions - the APS-DRGs. HSS acknowledged several problems with the SDRGs, namely they:

- Collapsed DRGs across severity levels ignoring statistically significant differences in outcomes;
- Lacked a uniform clinical structure;
- Were difficult to understand and remember; and
- Did not categorize small groups effectively, often combining them with larger groups that were not similar.

However, HSS found value in using the underlying SDRG structure of refining severity and enhanced this structure by subdividing the SDRG classification system into resource-based severity levels and corrected the problems they saw in the SDRG system in that the APS-DRGs:

[7] HCFA. "Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity". June 2004.

- Do not aggregate severity classes within a consolidated DRG (CDRG);
- Apply an intuitive and easily explained uniform structure, based on a nationally recognized and clinically acceptable model to their DRGs;
- Revamp the current CMS newborn and neonate model based on a combination of birth weight and diagnosis;
- Go beyond the SDRG model in the handling of CC exclusion logic; and
- Support major CC exclusion logic in addition to MDC and DRG specific severity class exclusions

Additionally, HSS used the model underlying the consolidation of DRGs in SDRGs and enhanced this system by adding a risk assessment function. This resulted in a hybrid-like technology built upon the foundation of former DRG technologies and adding a component of risk adjustment discussed in further detail in the section on "Quantifying Patient Severity: Weight Setting Methodology".

Since the development of the original APS-DRGs, Ingenix, through HSS, has created the Medicare modified APS-DRGs to address the current needs of CMS. Like the original APS-DRGs, the modified APS-DRGs are a consolidated version of CMS DRGs and can easily be traced to their origins. By contrast, the CSA-DRGs have undergone several iterative processes in order to develop their base DRGs, beginning with the adoption of the AP-DRGs that are not based on the CMS DRGs that are currently in use. The value of the simplicity in origin offered by the modified APS-DRGs is that the system can be more easily understood, may be more easily implemented, and offers more flexibility in terms of adding new refinements as changes occur without resulting in complex algorithms that become opaque.

Consolidation of DRGs and Assignment of Severity Levels

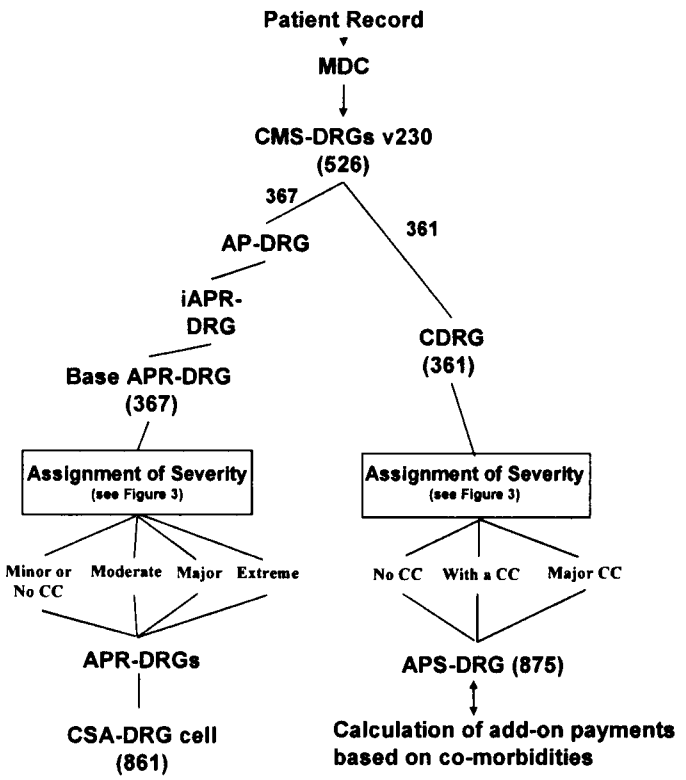
The systems developed by Ingenix/HSS and 3M have methodological differences in how they consolidate DRGs and evaluate and determine severity levels. There are, however, some basic similarities in approach, starting with the way each has developed base DRGs through consolidation so they more closely reflect the Medicare patient population and volumes. They exclude those DRGs that are not relevant in a Medicare-oriented system.

Figure 2 illustrates the decision logic of the final severity and DRG assignments arrived at through each proposed methodology. The left branch of ***Figure 2*** demonstrates that the CSA-DRG proposal entails more iterations and complex algorithms following the initial identification of the base DRGs at the AP-DRG level. The diagram demonstrates the simpler approach proposed by Ingenix, on the right branch. The APS-DRGs originate directly from current CMS-DRGs which are then consolidated and, following initial severity and DRG assignments, are further modified by adding a risk adjustment factor and increasing the weight assignment based on the additional severity of the particular case based on additional independent CCs.

APS-DRG Methodology

The right branch of *Figure* 2 illustrates APS-DRG's decision logic by mapping the process by which a final DRG is assigned and includes an additional step to reflect additional adjustments that refine the severity of the APS-DRG based on the number of additional co-morbidities.

Figure 2: Decision Logic



APS -DRGs consolidate DRGs using the same underlying structure of the SDRGs as developed by HCFA, in which all DRGs with and without CCs were consolidated into "CDRGs" as identified in *Figure* 2. In the Medicare modified version of APS-DRGs, DRGs unrelated to the Medicare population were removed. Using this methodology, HSS was able to reduce the number of CMS DRGs (526) to 361 CDRGs, reducing the total number of Medicare modified APS-DRGs to 875 (from 1,154) without compromising the system's ability to appropriately reflect resource consumption or severity. This also leaves enough additional three digit numbers open for new DRGs to be added as new technologies and treatments are developed that require system modifications.

APS-DRGs arrived at 875 total DRGS by splitting CDRGs into three resource-based severity levels: 1) no CCs, 2) with a CC, or 3) with a Major CC. Severity class is obtained by evaluating all independent secondary diagnoses of a patient, taking into account all CCs present, and resulting in a severity class that is detailed, comprehensive, and patient specific.

In addition, the APS-DRG system verifies any CDRG-specific severity class (CC) exclusions that may exist for an individual patient.

Figure 3, below, is based on 3M's assignment of severity chart as provided in the April 26, 2006 NPRM. This figure has been revised to highlight the proposed steps that modified APS-DRG and APR-DRGs (which are the basis of the proposed CSA-DRGs) have in common. Those boxes which are shared are shaded and in italics. The non-shaded boxes apply only to the APR-DRG system, which is the basis for the proposed CSA-DRGs.

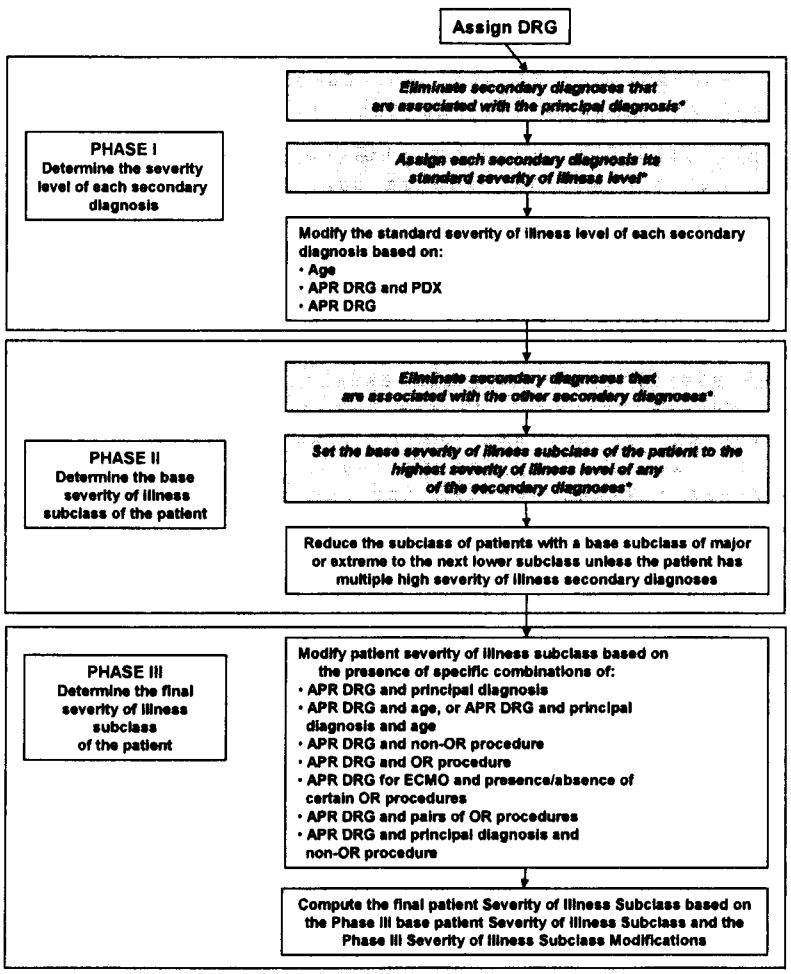
There are 19 steps involved in APS-DRGs assignment of severity (these steps are outlined in the APS-DRG Definitions Manual) prior to the risk and weight adjustments. There is no aggregation of severity classes in this model.

The Proposed Rule in the Federal Register notes that "Section 1886(d)(4) of the Act specifies that the Secretary must adjust the classifications and weighting factors at least annually to reflect changes in treatment patterns, technology, and other factors that may change the relative use of hospital resources. Therefore, we believe a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system."

Since APS-DRGs are derived directly from current CMS DRGs, they also account for complexity of procedures in the same way that current CMS DRGs do. For example, two CMS DRGs exist that differentiate between coronary angioplasty with or without stents, attributing the separate DRG to recognize the difference in complexity with the understanding that the patient may not be more severely ill. Thus, APS-DRGs reflect not only severity of illness, but also capture the complexities that exist and are already recognized through CMS' current DRGs.

The following is an example, provided by Ingenix, of how the APS-DRGs system of add-ons work:

Figure 3: Assignment of DRGs in both the APS-DRG and APR-DRG system



*Shaded boxes in italics indicate shared processes by APS-DRGs and APR-DRGs. Boxes that are unshaded indicate APR-DRG steps only.

A 73-year-old Medicare beneficiary is hospitalized with pneumonia and multiple coexisting clinical conditions as follows:

Diagnosis	Description	Status
486	Pneumonia, Organism NOS	Principal
402.91	Hypertensive Heart Disease with Failure	CC
496	Chronic Airway Obstruction NEC	CC
427.32	Atrial Flutter	CC
428	Congestive Heart Failure NOS	CC

244.9	Hypothyroidism NOS
533.9	Peptic Ulcer NOS
311	Depressive Disorder NEC

The principal diagnosis of 486 (Pneumonia) means that this case will be assigned to MDC 04, Diseases and Disorders of the Respiratory System. The first four secondary diagnoses are all considered CCs under the CMS DRG system as well as under APS-DRGs®. For this reason, the case will group to CMS DRG 089, "Simple Pneumonia and Pleurisy, Age>17, with CC." Under APS-DRGs, the case groups to 0891, which is also "Simple Pneumonia and Pleurisy, Age>17, with CC." Three (3) CCs are not used for assigning the discharge to a casemix category.

Under Medicare Modified APS-DRGs, the example changes in two ways. First, the CDRG is renamed to "Simple Pneumonia and Pleurisy" because pediatric splits have been eliminated. In addition, applying CC exclusion logic to the individual secondary diagnoses eliminates one CC from use in constructing the case-specific weight for this discharge. Specifically, 428.0 ("Congestive Heart Failure NOS") is disqualified from CC status because 402.91 ("Hypertensive Heart Disease with Failure") is also coded on the record. Modified APS-DRGs will assign this case to category 0891 with 2 independent "unused" coexisting clinical conditions with CC status.

Assume that APS-DRG 0891 has a baseline weight of 0.5258 and that each independent CC carries an adjustment factor of .23345 for medical cases in MDC 04. The final weight for this patient is 0.9927, calculated as follows:

A	Baseline Weight	0.5258
B	No. of Ind. CCs	2
C	MDC 04 Medical Adj. Factor	0.23345
A+BxC	Final Weight	0.9927

Development of APS-DRG Casemix Weights

All casemix-based payment systems need to develop a set of weights. In systems using mutually-exclusive cells (e.g., the current CMS DRGs), this process is straightforward. One simply calculates the mean cost for each cell and the mean across all cells. The ratio of the two constitutes a set of weights.

Ingenix decided that its payment for each case would be the sum of a base payment (the payment if no CCs) plus an add-on for each additional minor CC plus another add-on for each additional major CC. Therefore, if a DRG had an add-on payment of X for when a case had one major CC, its add-on payment would be 2X if a case had two major CCs.

As APS-DRGs are a hybrid system, development of its weights entails a two-step process. The first step involves calculating the weights for base payments for each DRG. These are calculated by taking the cases with no CCs and, as above, calculating the mean for each DRG.

The second step involved calculating the add-on percentage for each minor CC and major CC. Working with the cases have at least one CC, Ingenix first calculated the percent deviation as

PD = (actual cost/predicted cost) -1

where the denominator is the mean cost for a DRG as calculated in the first step. In a case-level analysis, this percent deviation is regressed on the number of minor CCs and major CCs as follows:

PD = B1*NCC + B2*NMCC

where NCC is the number of minor CCs, NMCC is the number of major CCs, and the Bs are coefficients to be estimated. (Note, the intercept was suppressed.)

Ingenix chose to run this regression separately for medical and surgical cases for each major diagnostic category (MDC). Given the tradeoff between bias and statistical power, this decision has face validity.

These parameters are used to calculate payment as follows:

W * (1 + B1*NCC + B2*NMCC) * CF

where W is the weight for the relevant DRG and CF is a conversion factor applied to all DRGs. Thus, within this MDC and medical-surgical split, there is an add-on payment of B1 percent for each minor CC and of B2 percent for each major CC.

CSA-DRG Methodology

By contrast, CSA-DRGs incorporate consolidated APR-DRGs with four complexity subclasses: 1) minor or no CC, 2) moderate, 3) major, and 4) extreme. The assignment of a patient to a subclass is a three phase process containing 18 steps. In the first phase, the complexity level of each secondary diagnosis is determined. The second phase determines a base complexity subclass for the patient based on the patient's secondary diagnoses. In the third phase, the final complexity subclass for the patient is determined by incorporating the impact of principal diagnosis, age, non-operating room (non-OR) procedures, and multiple combinations of categories of secondary diagnoses.

Further complicating severity assignment within the APR-DRG system, APR-DRGs also introduced a "re-routing logic" that "reassigns a patient to a new MDC and APR DRG in certain circumstances where the principal diagnosis is overly broad or the sequencing of principal and secondary diagnosis is unclear."[8]

This logic becomes difficult to follow given the complex algorithms used to adjust for severity, and can present difficulties for coders due to its lack of transparency. For example, without the ability to determine which codes are the most crucial to include on a hospital UB-92, hospitals who do not submit claims electronically will have no way of knowing which 9 diagnoses and 6 procedures are the most crucial to include on the forms. This lack of knowledge may result in

[8]Averill, et al. "All Patient Refined Diagnosis Related Groups (APR-DRGs) Methodology Review version 23.0 . 3M Health Information Systems. 2006.

decreases in productivity across such hospitals and coders having to devote more time to identifying every possible code and choosing which to use without the decision trees and instructions that have always been available to them during the DRG assignment process.

In addition, unlike APS-DRGs, CSA-DRGs do not account for differences in complexity among different DRGs. The Proposed Rule in the Federal Register states, "If Medicare were to adopt a severity DRG system based on the APR DRG logic but assign cases based on complexity as well as severity as we do under the current Medicare DRG system, such a distinction would represent a departure from the exclusive focus on severity of illness that currently forms the basis of assigning cases in the APR DRG system."

Thus, our evaluation of the APS-DRG and APR-DRG systems indicates that APS-DRG severity assignment process offers several advantages over the complexities of the APR-DRG, and consequently, the CSA-DRG system. Assigning severity levels within the APS-DRG system is a transparent and flexible process that is translatable and able to be replicated by one choosing to understand it. This increases the chances of coders properly following program rules and being efficient in the coding process, as well as potential public acceptance of a severity-based patient classification system.

B. Comparing Transparency, Costs and Public Availability

Transparency and the corresponding ability for the public to understand and work with the system selected will be a key part in not only gaining acceptance of the new approach but also limiting implementation and maintenance costs. By continuing to offer a system that is visible and understandable to end users, CMS will be keeping an important tradition of involving the stakeholders in the development and refinement of the system to ensure it is as accurate and fair as possible.

To date, CMS has not provided adequate documentation that includes CC lists and the exclusion logic tables to allow users to fully understand the patient classification and the proposed CSA-DRG assignment process. This may be in part due to the iterative approach taken in refining the system. Some decisions appear to have been made based on different combinations of secondary diagnoses and potential exclusions that make it no longer possible to reconstruct how one might arrive at a specific DRG without using a computerized program. It is our conclusion that the CSA-DRGs are more difficult for potential users to understand than the modified APS-DRGs.

Regardless of which proposal is ultimately selected, CMS will incur some costs in refining the approach both before the issuance of a final rule and throughout implementation and beyond. The less significant the changes are in terms of the overall structure of the classification system, the fewer costs that will be incurred for both the government and provider community. The CSA-DRG system and its apparent multitude of complicated algorithms, although carefully conceived over many years of research and development, make it less transparent, flexible, or amenable to later refinement and modifications. By decreasing the amount of transparency when introducing such new systems, CMS may ultimately increase its implementation and maintenance costs beyond what might be required to implement the modified APS-DRGs.

Given the current budgetary environment, limiting costs of implementing and maintaining any changes in the DRG system, as well as keeping the impact of the changes budget neutral, remain a high priority. The modified APS-DRGs, because they are an extension of the current system with the addition of a risk adjustment feature, will likely limit implementation costs and offer greater administrative ease, as well as the ability to more easily modify and refine the system moving forward.

C. *Ability to Systematically Predict Treatment Costs*

Modified APS-DRGs perform statistically at least as well as CSA-DRGs, and both perform substantively better than the current set of DRGs.

In terms of their ability to explain variance, modified APS-DRGs perform at least as well as CSA-DRGs and, in fact, slightly better. This is true at both the case level and hospital level. (See the table for the regression results and the appendix for a discussion of the underlying methodology used by The Lewin Group in its analysis.)

At the hospital level, the casemix coefficient is higher than 1.0 (and statistically significant) for all three casemix systems. It is 1.36 for the current set of CMS DRGs, 1.20 CSA-DRGs, and 1.07 for the modified APS-DRGs. Because IPPS payment is proportionate to casemix but the regression implies a more-than-proportionate relationship between cost and casemix, high-casemix hospitals are being underpaid relative to low-casemix ones, even after accounting for the add-on payments for teaching and disproportionate share percentage. This problematic pattern would be substantially greater under CSA-DRGs than under modified APS-DRGs.

There are several possible explanations for this pattern of greater-than-proportionate relationship between cost and casemix. First, this hospital-level finding is consistent with "compression," an important issue in all payment systems. The concern here is that the DRG weights are too low for expensive DRGs and too high for inexpensive DRGs, such that the range of payment is "compressed." However, the casemix coefficient is about 1.0 in case-level regressions for all three DRG systems, suggesting that weights themselves are not the problem here.

More plausibly, <u>within</u> a given DRG (or more precisely, within a payment category), high-casemix hospitals have more expensive patients than low-casemix hospitals. This could result from either:

- Heterogeneity of severity within each payment category, with higher mean for high-casemix hospitals; or
- Some other factor that is correlated with having a high casemix. For instance, the payment mechanism has not controlled for all aspects of teaching hospitals.

However, the fact that the greater-than-proportionate pattern is greatly diminished with modified APS-DRGs suggests that its cause is within-payment-category heterogeneity for the current DRGs and CSA-DRGs. Thus, CSA-DRGs would underpay high-casemix hospitals substantially more than APS-DRGs.

In sum, modified APS-DRGs explain at least as much variance as CSA-DRGs and would underpay high-casemix hospitals substantially less.

IV. CONCLUSION

Irrespective of which system CMS eventually chooses to improve its ability to reflect severity, it is incumbent upon CMS to make the grouper logic transparent and publicly available at a minimal cost. This will encourage on-going public discussion and open evaluation of the potential alternatives prior to the final adoption of a severity adjusted DRG system.

After a careful assessment, The Lewin Group has concluded that the modified APS-DRGs are worthy of consideration by CMS and the general public as an alternative to the proposed CSA-DRGs. They offer a simpler, more transparent, and perhaps more accurate approach by essentially extending CMS' approach to DRGs to date and adding the value of the CMS risk adjustment methodologies already used for capitated and psychiatric services to all DRG severity weight assignments. APS-DRGs are statistically sound, offer system stability and flexibility over time, and are both precise and comprehensive.

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Appendix A: Methodology of Regression of Cost on Casemix Measures

For each of the three casemix measures considered here, The Lewin Group regressed cost-per-case on the casemix weight to investigate two questions:

- Would hospitals be paid fairly? That is, would average payment to a hospital (across all its cases) be closely related to its average costs?
- Would payment for each case be closely related to its cost? Here the issue is not fairness per se but rather the potential for "cherry-picking," the potential for a hospital to design policies that would result in a disproportionate percentage of cases that were less expensive to treat than others receiving the payment rate?

To address the hospital-level fairness issue, we performed a hospital-level regression analysis. We examine the "cherry-picking" issue by conducting a case-level regression analysis.

Data

We obtained case-level charge data from 2004 MedPAR (Medicare Provider Analysis and Review) file. From the Medicare Inpatient Impact File, we obtained the cost-to-charge ratios (for operating and capital expenses), CSA-DRG weight, and several variables used to calculate Medicare's payment:

Wage = wage index used under IPPS,
COLA = cost-of-living adjustment (COLA, which equals 1.0 for all states except Alaska and Hawaii),
IRB = payment adjustment factor for teaching hospitals, and
DSH = payment adjustment factor for disproportionate share (DSH) hospitals.

From the Impact File also came:

two cost-to-charge ratios:

Ratio of operating costs to total covered charges and
Ratio of capital costs to total covered charges,

and two outlier variables:

Out_op = operating outlier payments as a percentage of operating IPPS payments and
Out_cap = capital outlier payments as a percentage of capital IPPS payments.

Ingenix/HSS calculated the casemix weight for each case for the current CMS DRG and the modified APS-DRG.

The cost for each case was calculated as the covered charges times the sum of the two charge ratios.

The case-level file was aggregated to the hospital level, with variables for cost per case and weight per case (i.e., casemix index).

Specification

Regressions of cost on casemix typically take one of two forms. In "payment regressions," cost per case is standardized for payment variables (other than casemix) before being regressed on casemix index. In "explanatory regressions," cost per case is regressed on casemix index and other variables related to payment. Both forms of regressions may include variables that are unrelated to payment.

As the conclusions drawn from the two sets of regression are the same, we present only the results for the payment regressions, as they are the simpler of the two.

Cost per case was standardized as follows:

Cost/ [(.70*wage + .30*COLA) (1 + IRB + DSH)].

Although outliers affect payment, there is no straight-forward way to use them to standardize cost.

A double-log regression was used, so the log of standardized cost per case was regressed on the log of casemix. The logarithms of each of the two outlier percentage variables (plus one) were also entered in this regression. So the regression was specified as follows:

Log(standardized cost per case) = B0 + B1*log(casemix index) +
B2*log(out_op+1) +B3*log(out_cap+1)

Alternative Casemix Measures as Predictors of Cost-per-Case Standardized by Payment Variables: Hospital and Case Levels

		Hospital Level			Case Level		
		CMS DRGs	CSA-DRGs	APS-DRGs	CMS DRGs	CSA-DRGs	APS-DRGs
Casemix							
	CMS DRGs	1.360			0.981		
		(41.20)			(2927.49)		
	CSA-DRGs		1.203			0.977	
			(44.08)			(3453.17)	
	APS-DRGs			1.072			0.974
				(46.11)			(3551.14)
Outlier % of payment							
	Operating	0.39	0.33	0.52	0.89	0.70	0.73
		(2.68)	(2.35)	(3.78)	(143.24)	(121.82)	(128.29)
	Capital	0.54	0.56	0.50	0.43	0.44	0.44
		(4.54)	(4.83)	(4.33)	(82.50)	(90.05)	(91.98)
Intercept		8.41	8.50	8.55	8.65	8.70	8.71
R-square		0.419	0.446	0.464	0.436	0.517	0.530
F		812.7	906.4	976.4	>1m	>1m	>1m
N		3389	3389	3389	11.6m	11.6m	11.6m

m = million. "CMS DRGs" are the DRGs currently used by CMS. APS-DRGs have been modified for Medicare. T-values are in parentheses. All variables are in logarithmic form.
Source: MedPAC and Impact Files.

156

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June 12, 2006

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Re: Medicare program; proposed changes for severity stratification [CMS-1488-P]

Dear Dr. McClellan,

Cardinal Health is pleased to submit these comments in response to the recent CMS proposal for changes to incorporate severity of illness into both the current and any future DRG system. We applaud your ongoing efforts to improve the quality of care for Medicare and Medicaid—in particular, your work to improve accountability in health care by bringing severity stratification into the reimbursement process. This is an important element in the movement toward payment for performance. We share your desire to ensure that hospitals are paid fairly based on accurate assessment of severity of illness.

Cardinal Health, Inc. is a global company serving the health care industry. Through one of our divisions, MediQual, we have extensive experience that is particularly germane to the issues raised by CMS' proposed changes. In more than 20 years of supporting the Pennsylvania Healthcare Cost Containment Council (PHC4), we have worked with both claims data and objective, physiologic, clinical data that reflect hospital care delivered to millions of patients. This extensive experience provides us with the insight to address critical issues in the development and use of optimal risk-adjustment methodologies. The evidence and our experience underscore these critical lessons:

- The use of objective, physiologic data on admission to enhance claims data significantly improves the accuracy of any severity stratification.
- Outside of principal diagnosis, laboratory results are the single most important predictor of severity.
- The addition to claims data of time-stamped laboratory results on admission resolves a key problem in distinguishing co-morbidities present on admission from complications during hospitalization.
- For purposes of estimating severity, electronically capturing laboratory results will require less time and fewer resources than incrementally improving coding practices, which may never achieve the accuracy and consistency of the laboratory results themselves.
- Credible risk adjustment based upon objective, physiologic data increases the likelihood of clinician acceptance and is critical to public reporting and pay-for-performance.

In the past, the cost to acquire physiologic data presented a barrier to their widespread use. Today, technological advances have made it possible to electronically capture laboratory results at a cost similar to that of capturing claims data alone. Michael O. Leavitt, Secretary of Health and Human Services, has repeatedly stressed the importance of electronic transmissibility of laboratory data.

The rapid growth of public reporting underscores the importance of ranking hospital performance accurately. Numerous publications have suggested that the use of claims data alone to determine severity can result in misclassification of hospital performance. Severity-adjusted mortality rates are a common measure of hospital performance. Analyses of our research database demonstrate that predicting severity rates using claims data alone could incorrectly rank up to 45% of top-performing hospitals.

The remainder of this document discusses these key issues related to the current CMS proposal and provides data analyses and an annotated review of the literature to support our positions and recommendations. An appendix contains supplemental tables, figures, and a detailed bibliography.

NEED FOR CHANGE

As detailed in the following sections, a growing body of evidence suggests the need for an objective, precise, and accurate approach to stratification of severity. This is especially true given the undesirable variability in documentation of patient records and in the coding process itself. Claims data are based on data from both accurate and inaccurate coding. These mixed-quality data form the basis of any system that relies solely on claims data, including the severity-adjusted-DRGs proposed by CMS.

It is also important to recognize that the proposed 861 consolidated severity-adjusted DRGs do not reflect the severity of illness of hospitalized patients on admission; rather, they reflect the burden of illness experienced by patients during the entire course of their hospital stay. This is a critical distinction. The ideal system to link hospital payment to severity of illness would estimate severity at the time of admission. On the other hand, using any severity-stratification system that is based on the total burden of illness during the entire course of the hospitalization, CMS could pay for complications that result from potentially sub-optimal care. Thus, severity adjustment based on the total burden of illness during hospitalization—as solely claims-based systems are—can undermine the very principles that pay-for-performance programs are designed to advance.

The ability of a severity-adjustment methodology to distinguish between co-morbidities and complications is crucial. Claims data cannot always separate secondary diagnoses that are present on admission from those that occur during hospitalization. For example, metabolic abnormalities in hospitalized patients are excellent predictors of increased severity, but current documentation and coding practices do not provide reliable information about the presence, absence, or degree of metabolic abnormalities. Such unreliability makes comparisons based on these codes suspect. This would be true even if a "present on admission" flag were added to the codes. If an abnormality is missed, it cannot be coded and cannot be flagged. Furthermore, even if the laboratory abnormality is coded, the degree of abnormality, which strongly predicts severity, would still not be available.

In contrast, the use of time-stamped physiologic data on admission provides the objective evidence that is the cornerstone to ensuring fair and accurate estimates of severity on admission. Physiologic data that are predictive of severity include laboratory results, vital signs, and other clinical indicators, such as neurological status at the time of admission. Laboratory results, which are widely available, provide the most immediate opportunity to include objective, physiologic evidence on admission for a cost-effective enhancement to claims-based severity estimates. Since data collection is already automated for both the claims data and the laboratory results, manual abstraction is unnecessary. In 2006 an estimated 95% of hospitals have the capability to capture laboratory results electronically.

The combination of time-stamped laboratory results with claims data provides an accurate measure of illness at the time of admission and enhances acceptance by clinicians. This approach ensures that events that occur following admission do not bias the estimate of the patient's severity at the time of admission. Unlike severity measures that are solely claims-based, such as those in the current CMS proposal, the use of objective, time-stamped, physiologic data on admission greatly reduces the potential for inaccurate quality assessment or improper payment due to imprecise documentation and coding.

Given the growing momentum of pay-for-performance and gainsharing initiatives, and given that the CMS plan is designed to be revenue neutral, it is imperative to ensure that the proper groups are being

rewarded. In the absence of an objective, admission-based, physiologic severity-adjustment approach, pay-for-performance and gainsharing programs could reward the wrong parties. This underscores the critical importance of which severity methodology CMS selects.

While it may be difficult or impossible for CMS to shoulder complete responsibility for maintaining any grouping and severity-adjustment system, the use of a single, non-public organization to provide both the resource-estimation grouping and the severity-adjustment system may eliminate important checks and balances. The use of a separate severity estimate based on objective, physiologic data—either to stratify severity or to serve as a cross-check of the proposed CMS system—would add substantial credibility. The use of an open methodology that utilizes objective, time-stamped, physiologic data on admission also adds a level of transparency that would facilitate hospital and clinician acceptance.

INTRODUCTION TO THE EVIDENCE

Pennsylvania holds the singular distinction of being the only state in the union to have a 20-year, uninterrupted history of reporting objective, admission-based, risk-adjusted outcomes across a wide variety of medical conditions. The reporting agency is the Pennsylvania Health Care Cost Containment Council (PHC4) located in Harrisburg, Pennsylvania. The Commonwealth of Pennsylvania has used us as the exclusive source for their risk-adjustment methodology since the inception of PHC4. For the past 20 years we have established the data definitions, performed the data collection, and developed the objective, admission-based, risk-adjustment methodology used for public reporting of hospital performance in the Commonwealth of Pennsylvania. Our extensive experience is based on having had access to this unique dataset.

From the outset, PHC4 has believed that clinical data beyond those which can be obtained from claims data are required to achieve the accuracy, consistency, and clinical acceptance required for public reporting. The Pennsylvania Medical Society endorsed this stance during the legislative reauthorization process for PHC4 in 2003, saying, *"The Pennsylvania Medical Society supports reporting as long as it is clinically based and risk-adjusted."* Through this long relationship with PHC4 we have extensive experience using claims data enhanced with objective, time-stamped laboratory results, vital signs, and other measures of physiologic status. Two decades of experience has shown us that an ounce of data improvement is worth a pound of changes in statistical methodology.

Michael Porter and Elizabeth Tiesberg, in "Fixing Competition in U.S. Health Care" (*Harvard Business Review Research Report,* 2004), list the use and analysis of *"the wrong information"* as one of the root causes for the failure of competition. In the section "Identifying Root Causes," the authors state, *"There have been isolated efforts to collect the right kind of information, among them Cleveland Quality Choice, the Pennsylvania Health Care Cost Containment Council, and New York State's CSRS."* It is important to note that all three of these organizations use objective, time-stamped, physiologic data on admission for severity adjustment. Porter and Tiesberg compliment both the organizations and the data.

A further compliment to these data has been their secondary uses by other medical investigators. One of the most important examples is the development of the Pneumonia Severity Index by Fine et al (*N Engl J Med* 1997). This index may well be the most widely used methodology for severity stratification of patients with community-acquired pneumonia. Another important secondary use of these data is Silber's Failure to Rescue metric (*JAMA 1995)*, which has been accepted as one of the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Indicators. Other predictive risk scores using these data have been published for various disease states, including pulmonary embolism and congestive heart failure.

AHRQ is just completing an independent study which bears on many of these issues. The study, "Adding Clinical Data Elements to Administrative Data for Hospital-level Reporting" [AHRQ Contract #233-02-0088], is under the direction of Anne Elixhauser, PhD. This study was commissioned by AHRQ to conduct a cost-benefit analysis of the incremental value of adding clinical data such as laboratory results, vital signs, and other clinical indicators to claims data for the purpose of hospital-level quality reporting. A formal report is expected to be available in July 2006. Evaluating the AHRQ report will provide important information to help guide CMS' selection of the optimal, cost-effective system.

RECOMMENDATIONS

Based on evidence and experience, we recommend that any changes to the current DRG system that include severity stratification include objective, time-stamped, electronically captured laboratory results.

Given the high complexity of this issue and the potentially large impact on hospital reimbursement and quality rankings, it would be prudent to conduct one or more demonstration projects studying claims data enhanced with objective, time-stamped, electronically captured laboratory results as an alternative approach for severity adjustment for payment and quality assessment purposes. This would allow time to garner more information to ensure that a severity component is successfully added to changes in the payment system.

We would welcome the opportunity to meet with CMS to discuss these issues as they pertain to pay-for-performance initiatives, public reporting, and the proposed changes to the DRG reimbursement system.

Respectfully yours,

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Supporting Evidence for Cardinal Health Response to CMS-1488-P

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June 12, 2006

Table of Contents **Page**

I. Potential Misclassification of Hospital Performance Using Claims Data

Section Summary

Results of our analyses that compare risk-adjusted hospital mortality ranks using claims and physiologic models showed a misclassification of up to 45% for top-performing hospitals with models based on claims data. We believe that such misclassifications can impact public reporting of outcomes and payment-for-performance programs.

The medical literature and analyses of our data, which include electronically captured laboratory results, suggest that laboratory results provide the most immediate opportunity to include objective, physiologic evidence on admission for a cost-effective enhancement to claims-based severity estimates.

We suggest that it would be prudent to conduct one or more demonstration projects studying claims data enhanced with objective, time-stamped, electronically captured laboratory results as an alternative approach for severity adjustment for payment and quality assessment purposes.

A. Review of Internal Research

- To examine the potential for misclassification of hospital performance as a function of the risk-adjustment methodology used, our research database was evaluated for seven disease groups (congestive heart failure [CHF], pneumonia, sepsis, acute myocardial infarction [AMI], respiratory failure, diabetes mellitus [DM], and stroke) to determine the correlation between claims-based risk adjusted rankings and those based on physiologic data on admission. The physiologic risk-adjustment models used were those currently being used for public reporting in the Commonwealth of Pennsylvania.

- Claims-based risk-adjustment models were compared with two different physiologic-based models: (a) a physiologic laboratory model (PLM) that used laboratory results on admission plus claims data, and (b) a physiologic full model (PFM) that used laboratory results, vital signs, and clinical characteristics on admission, plus claims data. Each hospital's risk-adjusted mortality was computed as a standardized mortality ratio, and these were ranked from 1 to n. A perfect correlation (i.e. complete agreement) between the results achieved between any pair of models in a figure would appear as the complete agreement of plot points with no scatter, i.e. along a straight line.

- As can be seen from Figure 1 (a, b, and c) for heart failure, the agreement between PLM and PFM is greater (less scatter) than between claims data (more scatter) and either PLM or PFM.

Figure 1 (a, b, and c). Comparison of hospital level rank based on risk-adjusted mortality rate with claims, physiologic lab (PLM), or physiologic full model (PFM) for heart failure.

Figure 1a. Claims model vs. physiologic lab model

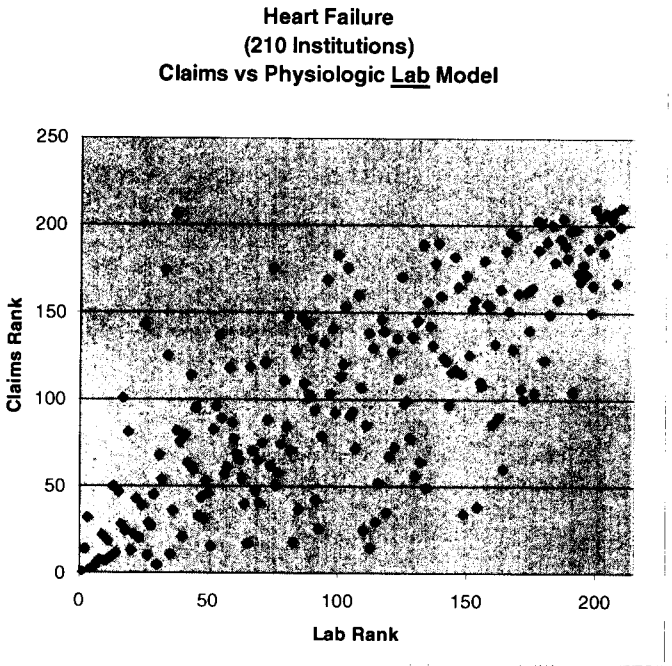


Figure 1b. Claims vs. physiologic full model

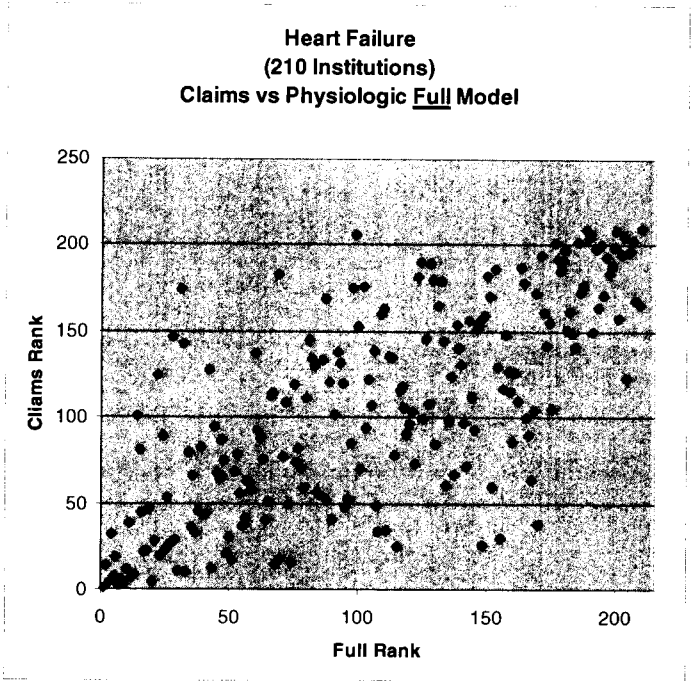
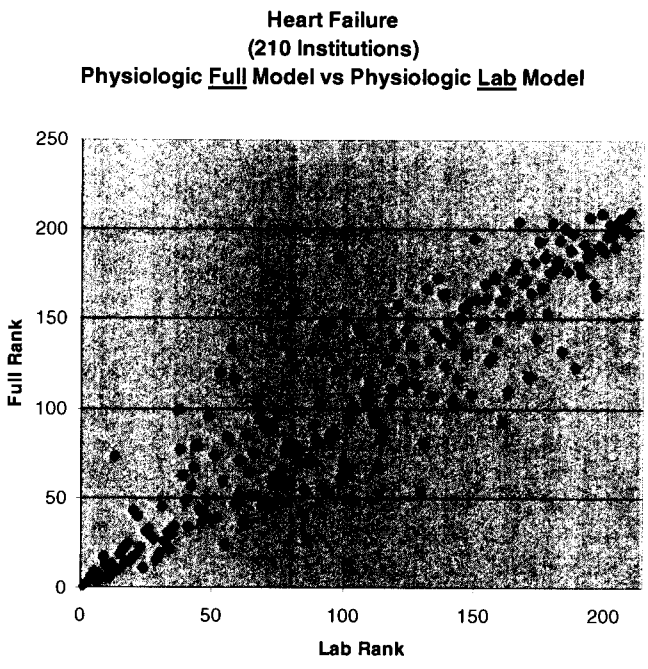


Figure 1c. Physiologic full model vs. physiologic lab model.



- A second analysis determined the degree of correlation between the claims models and the PLM and PFM models from the perspective of a pay-for-performance system that rewarded institutions that performed in the top two deciles (i.e. the top 20%). The top two deciles were chosen because this mirrors the cutoffs used in the Premier Pay-For-Performance Demonstration Project (http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1441). For each disease examined, the institutions that ranked in the top two deciles for risk-adjusted mortality using claims models were compared to those ranked in the top two deciles using either of the physiologic based models (PLM or PFM) to determine the extent of agreement between the models.

- Missed classification rates were calculated as follows: all hospitals whose performance exceeded the 80th percentile (i.e. the top 20%) using the claims-based adjustor formed the denominator. The numerator was the number of hospitals where both the claims based method and one of the physiologic-based models were in agreement. As shown in Table 1 the rates of misclassification between the claims-based ranking and either of the physiologic based rankings was substantial. The mean misclassification rate across the seven diseases was 28.8% (range of 7.7-45%). These findings provide further support for the usefulness of using models based on objective, time-stamped, physiologic data on admission, and specifically models based on laboratory results.

Table 1. Misclassification of high-performance hospitals based on hospital level risk-adjusted mortality rates in common diseases estimated using claims, physiologic lab, and physiologic full models.

Disease Group	Total Hospitals (n)	[illegible]	Misclassification* of Performance (%)	
			[illegible]	[illegible]
CHF	210	4.0	38.1	40.5
AMI	201	7.4	45.0	50.0
Pneumonia	210	5.6	19.1	21.4
Respiratory Failure	173	18.9	42.9	34.3
Sepsis	180	18.4	30.6	36.1
Stroke	188	6.1	18.4	31.6
DM	195	1.2	7.7	7.7

CHF = heart failure; AMI = acute myocardial infarction; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; PLM = physiologic laboratory model; PFM = physiologic full model;
* Defined as: Hospitals that are in the top two deciles of risk-adjusted mortality using claims models but not in the top two deciles by the physiologic model in the comparison

B. Literature Review:

- Many researchers have commented that claims data do not adequately measure risk, especially risk on admission. This was highlighted in recent policy statements by the American Heart Association in "Payment for Quality: Guiding Principles and Recommendations (Buffalino, Circulation 2006 113: 1151 – 1154)" and "Standards for statistical modeling used for public reporting of health outcomes (Krumholtz, Circulation 2006;113)," which stated the following:

- *"Use rigorous methodological approaches to measure quality of care. Quality-of-care measures should be risk-adjusted, standardized, and evidence-based. Rigorous methods should be used to measure quality, and these methods should include defining data standards and providing for consistency of measures. Quality measures should be based on clinical data to the greatest extent possible."*

- *"If administrative data are used, then quality measures should be validated against higher-quality clinically derived data. Use of the highest-quality methodological approaches will minimize the likelihood of misrepresentation of quality."*

- *"Models that use patient risk variables that may represent events that occurred as a result of the care provided may inadvertently reward hospitals that poorly manage their patients by allowing them to 'adjust' for conditions that arose as a result of deficiencies in care. Consequently, codes that could represent complications should not be included in risk models. Moreover, continuous efforts should be made to improve the administrative claims data so that it would be possible to differentiate complications from co-morbidities."*

- Other researchers have provided similar comments:

  - MacLean et al (Medical Care 2006) noted that, "*Scores based on administrative data may be of little value to large numbers of older patients whose health conditions do not match limited administrative data performance measurement. Additionally, performance scores based on administrative data alone greatly overestimate health care quality because performance is much higher for the portion of health care that can be assessed with administrative data relative to the portion that requires data from medical records.*"

  - An editorial by David Mark (JAMA 2001) on a study that used claims data (Jha et al. JAMA 2001) notes that, "*...it is important to realize that the data on which these results are based are often extremely limited with respect to the assessment of the severity of the patients' illness and other characteristics that may be risk factors for mortality or the outcome of interest.*"

    - In other articles, Mark has also commented that, "*Much evidence exists that clinical variables add important predictive ability to administrative data, (Iezzoni et al. Medical Care 1992)" and that, "...this additional predictive ability makes a difference in assessing factors associated with patient outcomes" (Hannan et al. Health Serv Res 1997).*

  - Halm (N Engl J Med 2001) also discussed that the, "*Administrative data cannot account for differences in severity of illness with any degree of clinical subtlety.*"

  - The limitations of claims data have also been highlighted in other studies and editorials, such as those by Jenks (*JAMA*. 1992), Jollis et al (*Ann Intern Med.*1993), Birman-Deych et al (*Med Care*. 2005), and Lawthers et al (*Med Care*. 2000).

- The inability of the proposed CMS changes to differentiate complications that occur during hospitalization from complications present on admission can have significant implications for payment programs. Several studies have highlighted this issue.

    - In one of Lisa Iezzoni's many contributions to the literature, namely, "The Risks of Risk Adjustment (*JAMA* 1997)," she commented that, "*Additionally, to draw meaningful conclusions on quality based on severity adjusted death rates, one must adjust only for preexisting conditions but not those arising late in the hospital stay – possibly because of iatrogenic complications.*"

        - In this paper, published almost ten years ago, Iezonni warned that, "*Our preliminary analyses agree with others in suggesting that discharge-abstract-based measures rely on late events to boost their predictive ability.*"

    - A limited number of studies have attempted to corroborate coded diagnosis using explicitly defined *a priori* criteria. Using such a methodology McCarthey et al (*Med Care.* 2000) found that substantial numbers of discharge diagnoses in both surgical and medical cases lacked documented evidence to support the discharge diagnosis in the medical records.

C. Section Conclusion:

- For six of the seven disease groups evaluated, there was greater agreement between the two physiologic models than between the claims-based model and either physiologic model. Diabetes was the only disease group evaluated where there was good concordance with the claims and both physiologic models (PLM and PFM). This shows that:

    - Compared to claims-based models, either physiologic model—PLM or PFM—provides a more accurate estimate of severity in patients with common disease states evaluated.

    - PFM provides the most accurate estimates.

    - Severity estimates obtained using PLM methodology correlates well with those obtained using PFM.

- Severity-adjustment models based on full physiologic data are the "gold standard." However, until laboratory results, vital signs, and other clinical indicators are all available electronically, this is also a more costly approach.

- Severity-adjustment models based on objective, physiologic data in the form of laboratory results currently offer a cost-effective alternative that, compared with models based solely on claims data, provides significantly more accurate severity estimates.

- It is important to note that in 2006 laboratory results can be captured electronically from 95% of institutions in the US, and use of the LOINC terminology facilitates the standardization of laboratory results.

- Thus, the medical literature and analyses of our data, which include electronically captured laboratory results, suggest that physiologic lab models may provide the most immediate opportunity for a cost-effective enhancement to claims-based severity estimates.

- We would suggest that further research, including CMS-supported demonstration projects, be done to explore such alternatives prior to implementation of any major change in CMS policy.

II. Errors of Omission: Physiologic Data vs. Claims Data

Section Summary

- Abnormal laboratory results are one of the most important predictors of severity. Our results show that claims data are able to identify common laboratory abnormalities 9.1% to 18.6% of the time.

- Even when laboratory abnormalities are identified by claims data, they are not time-stamped and thus do not differentiate abnormalities present on admission (possible co-morbidities) from those that develop during hospitalization (possible complications).

- Unlike claims data, the use of time-stamped laboratory results provide the granularity to differentiate risk at patient-specific abnormal values that are important in estimating risk on admission.

- Given the low rates of detection of laboratory abnormalities using claims data and the importance of abnormal laboratory results in estimating severity on admission, we believe that electronically obtaining laboratory results would be significantly less costly than incrementally improving detection of laboratory abnormalities using claims data, which may never achieve the accuracy and consistency of the laboratory results themselves.

A. Review of Internal Research

- Since ICD-9-CM codes do exist for some laboratory data, these codes can be used to compare the performance of claims data against laboratory results in identifying abnormal laboratory results. Using data from our research database, we examined claims data for hypernatremia [high serum sodium], hyponatremia [low serum sodium], hyperkalemia [high serum potassium], hypokalemia [low serum potassium], and anemia [low serum hemoglobin]. The research database for these evaluations included data from 83 institutions all of whom provide laboratory results electronically for the entire hospitalization using the laboratory results as the "gold standard".

- Abnormal laboratory results were defined as any value outside the upper and lower boundaries as found in Harrison's Principles of Internal Medicine (McGraw-Hill Professional; 15^{nth} Edition, 2001). Using these definitions, the sensitivity and

specificity were calculated for claims data, using electronic laboratory results as the gold standard. Laboratory results at any time during hospitalization were examined, as well those during the admission period, defined as the first day of stay. Thus, we were able to evaluate the ability of claims data to identify laboratory abnormalities present during the admission period as well as those during the entire hospital stay. Furthermore, we were able to determine the ability of claims data to identify cases in which there was unequivocal evidence of laboratory abnormalities, i.e. cases in which laboratory abnormalities were identified more than 10 times during the hospitalization.

- The results showed that while cases with pertinent laboratory abnormalities identified from laboratory results during the hospital stay, claims data only identified such cases 9.1%-18.6% of the time (table 2 below and tables 3-5 in the appendix).

Table 2. Sensitivity and specificity of claims data to detect common laboratory abnormalities* identified from 83 institutions that provide electronically captured laboratory results during hospitalization [refer to Tables 3-5 in the appendix for the raw data for each analysis described].

Laboratory Abnormality*	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
Low Serum Sodium (≤ 135 mEq/L)	9.7	99.8	95.0	72.5
High Serum Sodium (> 145 mEq/L)	9.8	99.9	85.0	96.1
Low Serum Potassium (< 3.5 mEq/L)	18.6	99.3	85.9	83.7
High Serum Potassium (> 5.0 mEq/L)	15.0	99.7	87.4	90.7
Low Serum Hemoglobin (< 12 g/dl for females, < 14 for males g/dl)	9.1	99.3	96.1	35.8

* Using Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15th Edition, 2001.
ICD-9 Codes used: Low serum sodium (271.61), high serum sodium (276.0), low serum potassium (276.8), high serum potassium (276.7), low serum hemoglobin (285.9).

- A subsequent analysis was done to determine the ability of the claims codes to detect laboratory abnormalities in the admission period. As shown in table 3 below, claims data were able to identify these abnormalities 9.6%-22.8% of the time. For all 5 codes examined, the specificity was uniformly very good, exceeding 99% in all cases. In other words, when claims data identified an abnormality that identification was correct. This is not unexpected since false positive identification of laboratory abnormality is uncommon. This also accounts for the high positive predictive values.

- However, the story for sensitivity is quite different. The hypokalemia code, which showed the best sensitivity, still only identified fewer than one in five cases of laboratory-confirmed hypokalemia. Three of the five codes examined identified fewer than 1 case in 10 using ICD-9-CM codes. When the identification was constrained to the first day of stay, the sensitivity did improve, but only by 2%-4% (table 3 below).

Table 3. Sensitivity and improvement of claims data to detect common laboratory abnormalities* identified on admission from 83 institutions that provide electronically captured laboratory results.

Laboratory Abnormality	Sensitivity Admission Period	% Improvement from Full Hospital Stay
Low serum sodium (< 135 mEq/L)	11.8	2.1
High serum sodium (> 145 mEq/L)	12.3	2.5
Low serum potassium (< 3.5 mEq/L)	22.8	4.2
High serum potassium (> 5.0 mEq/L)	18.9	3.9
Low serum hemoglobin (< 12 g/dl (females), < 14 g/dl (males)	9.6	0.6

* Using Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15nth Edition, 2001.
ICD9 Codes used: Low serum sodium (271.61), high serum sodium (276.0), low serum potassium (276.8), high serum potassium (276.7), low serum hemoglobin (285.9).

- Furthermore, we looked at the sensitivity of claims data as a function of the number of times the laboratory results were examined. Patients often have these laboratory values determined multiple times. Ignoring the important admission period sensitivity for the moment, we discovered that even in cases where laboratory studies were done more than 10 times, the claims data sensitivities never reached 50%. In other words, patients who had laboratory studies performed and documented more than 10 times were nevertheless identified less than half the time, and in the case of anemia, less than 10% of the time (see table 4).

Table 4. Sensitivity of claims data to detect common laboratory abnormalities* identified more than 10 times during the hospitalization from 83 institutions that provide electronically captured laboratory results.

Laboratory Abnormality	Sensitivity of Claims Data (%)
Low serum sodium recorded >10 times (≤ 135 meq/L)	30.0
High serum sodium recorded >10 times (>145 meq/L)	42.2
Low serum potassium recorded >10 times (< 3.5 meq/L)	19.5
High serum potassium recorded >10 times (> 5.0 meq/L)	20.4
Low serum hemoglobin Hgb recorded >10 times (<12 g/L for females or <14 g/L for males)	9.5

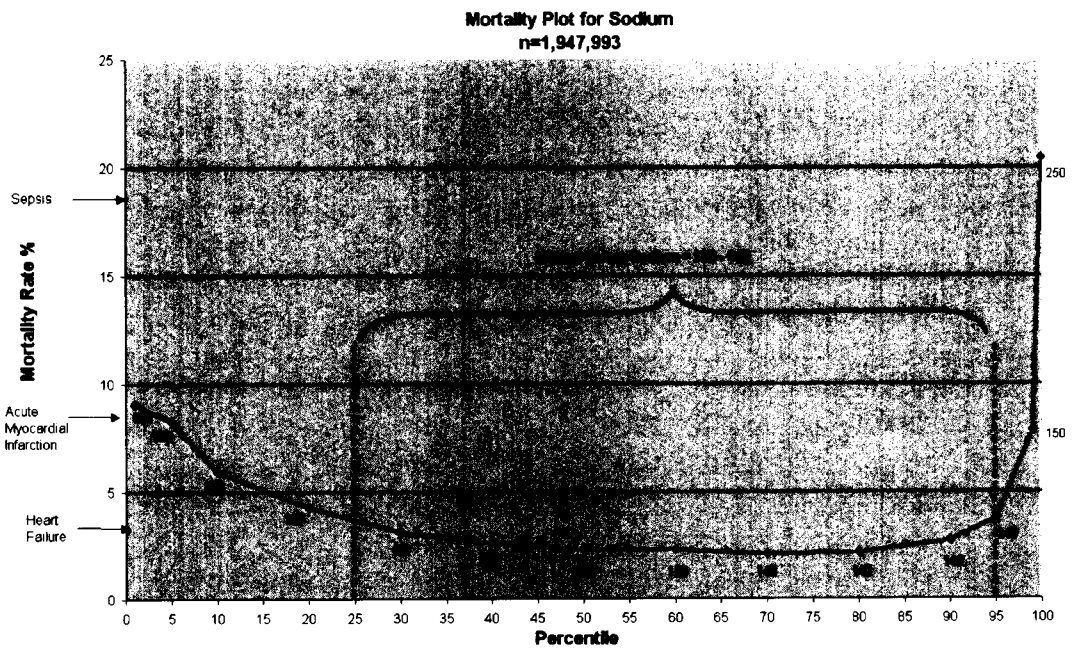
* Using Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15nth Edition, 2001.
ICD-9 Codes used: Low serum sodium (271.61), high serum sodium (276.0), low serum potassium (276.8), high serum potassium (276.7), low serum hemoglobin (285.9).

- The poor sensitivity of the claims data suggests that if the goal is accuracy then the one-time cost of obtaining laboratory results might well be less than the cost of incrementally trying to improve coding practices.

- Even when claims data do identify laboratory abnormalities, they still do not provide the granularity required to appropriately estimate risk. The importance of using severity models based on objective laboratory results is highlighted by the

results that show the relationship between mortality rates and the differing degrees of laboratory abnormalities (see figure 2 following and figures 8-12 in the appendix). Mortality plots were developed by plotting unadjusted, all-cause mortality rates against laboratory results that had been categorized into deciles. For example, the 90th to 100th decile represented the 10% of cases with the highest value measured for that laboratory test. The mortality plot for serum sodium is shown in figure 2 below. As can be seen from the figure, the mortality increases when the laboratory value becomes very low or very high. Compared to the mortality rate associated with normal serum sodium values, the mortality rate doubles on the low end and increases by nearly four-fold on the high end. Even if claims data were able to detect the presence of abnormal serum sodium, they would not accurately estimate risk because the actual laboratory result would remain unknown. These data demonstrate that it is not only important to identify cases with laboratory abnormalities dichotomously (present or absent), but that the actual laboratory result has further discriminatory power in predicting a patient's mortality. Mortality graphs for other laboratory results are shown in figures 8-12 in the appendix.

Figure 2. In-hospital mortality by serum sodium result from institutions that provide electronically captured laboratory results during hospitalization.



Note: Each plot point provides mortality at the serum sodium result (normal as per Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15th Edition, 2001). As mortality rate varies by disease group, the arrows adjacent to the y-axis indicate the hospital mortality for sepsis, acute myocardial infarction, and heart failure.

B. Literature Review

- Omissive variability occurs in circumstances where the claims data do not have the ability to capture risk factors that are important in accurately estimating severity. Claims data have been found to be insensitive in capturing laboratory

abnormalities that are significant predictors of poor outcomes. The following points summarize key studies:

- Renal insufficiency is an example of a critical risk factor that can be reliably identified on admission by abnormal laboratory results (i.e. serum creatinine or blood urea nitrogen). Such identification is important in risk stratification, because renal insufficiency on admission has been found to be a significant predictor for poor outcomes (e.g., hospital or 30-day mortality) in various diseases. These include pneumonia (Fine, *N Engl J Med* 1997), pulmonary embolism (Aujesky, *Am J Respir Crit Care Med* 2005), congestive heart failure (Auble, *Academic Emergency Medicine* 2005; Fonarow, *JAMA 2005*), acute myocardial infarction (Sjauw, *Am J Cardiol* 2006), coronary artery bypass graft surgery (Hannan, *J Am Coll Cardiol* 2006), and percutaneous coronary intervention (Wu, *J Am Coll Cardiol* 2006).

    - A recent study by Kern et al (Health Services Research 2006) found that, *"Depending on the detail of the algorithm, only 20.2 to 42.4 percent of individuals with CKD* [chronic kidney disease] *received a renal-related diagnosis code in either VA or Medicare records over 1 year."* This study concluded, "*Diagnosis codes in administrative records from Medicare and VA systems are insensitive, but specific markers for patients with CKD.*"

- Movig et al (*J Clin Epidem* 2003) studied the validity of claims data to identify patients with significant hyponatremia (low serum sodium). Results showed that of 2632 cases with significant hyponatremia identified by laboratory results, claims data were able to identify a maximum of 30% of these cases. They concluded, "*To assess the validity of case finding of patients with hyponatremia, the use of analytical techniques, such as certain laboratory measurements, is advisable.*"

- Best et al (*J Am Coll Surg* 2002) studied whether data from the National Surgical Quality Improvement Program (NSQIP) could be provided from the less costly administrative dataset. They concluded that, *"Sensitivity and positive predictive value of administrative data in comparison to NSQIP data were poor."* Additionally they stated that, *"We cannot recommend substitution of administrative data for NSQIP data methods."*

C. Section Conclusion

- Results of our analyses and reports in the literature show that claims data are unreliable in detecting laboratory abnormalities. Even if claims data are able to detect such abnormalities they are unable to provide the granularity required to estimate severity.

- This has significant implications to CMS as well as to hospitals, since the current CMS proposal for hospital payment is based on an estimate of risk. Thus, errors of omission can lead to adverse consequences for the current CMS proposal, since for reimbursement purposes it may prove difficult to accurately estimate severity using claims data alone.

- The use of time-stamped, physiologic data captured electronically on admission—i.e., widely available laboratory results—can minimize the undesirable variability described above by providing a more accurate basis for severity adjustment compared with reliance on claims data.

III. Risk Adjustment

Section Summary

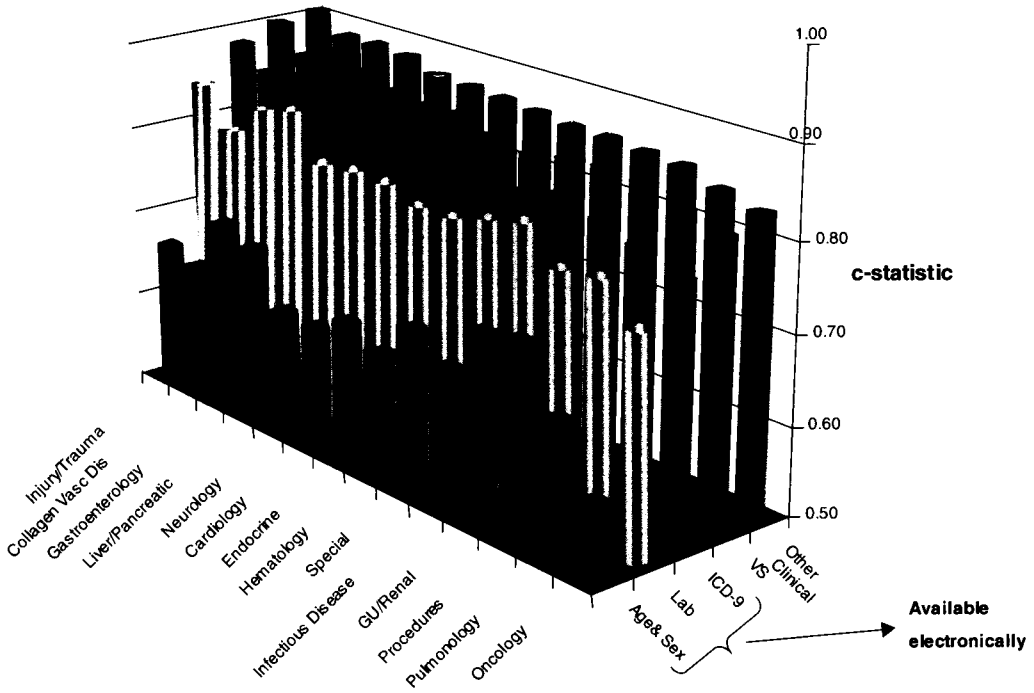
- In developing disease-specific severity-adjustment models, the largest increment in predictive power occurs with the addition of laboratory results.
- Disease-specific risk-adjustment models constructed with time-stamped objective physiologic data on admission consistently show c-statistic above 0.80, and thus demonstrate good predictive power.
- There are small differences between c-statistics (predictive power) found in our PLM and PFM models.
- C-statistics may not tell the entire story related to predictive power as inclusion of late hospital events that predict mortality can artificially inflate the c-statistic.

A. Review of Internal Research

- As PHC4 reports a wide variety of both medical and surgical conditions, a large number of disease-specific severity-adjustment models are required. Currently we divide the 114 disease-specific models into 17 large categories that correspond to the disease groupings found in the table of contents of any major medical textbook.
- We consider the parameters of risk to be five discrete, mutually exclusive groups of risk factors. These groups are demography (age and gender), laboratory results on admission, ICD-9-CM codes (claims), vital signs, and selected key clinical findings such as neurologic status at the time of admission. These models, which predict in-hospital mortality, were constructed using what are now quite standard logistic regression methods.
- Figure 3 following shows the increase in predictive power as estimated by the c-statistic that occurs as the various types of risk factors are included in the models (a c-statistic of 0.5 would indicate guesswork and a c-statistic of 1.0 would indicate perfect prediction). The mean and median c-statistics for the physiologic full models (PFM) across all categories are both 0.87 (range from 0.77 to 0.94). The mean and median c-statistics for the physiologic lab models (PLM) models across all categories are 0.84 (range from 0.60 to 0.93).
- The c-statistic does not tell the whole story since the use of claims data that confounds admission risk with complications can artificially inflate the c-statistic.

- Our sepsis, pneumonia, stroke, pediatrics, heart failure, and acute myocardial infarction models have been presented in major medical meetings (Tabak et al 2004-2005).

Figure 3. The relative contribution to the predictive power of the various parameters of risk across multiple disease categories.



B. Literature Review

- While there are published studies using claims data (Krumholtz et al; Circulation 2006; 113 and Circulation 2006; 113) showing that the predictive value of claims data approximates that of physiologic data, the studies are not based on the same data that would be used under the current CMS proposed changes. These studies used an all claims dataset across a 1-year period prior to index hospitalization to determine relevant risk factors for mortality.

    - The authors did use laboratory data within the first day of admission, however they chose to convert these data to simple dichotomous variables (present/not present) thereby limiting the predictive power of abnormal laboratory results as they become more extreme. For example, by making serum sodium dichotomous, the authors only evaluated hyponatremia, thereby both excluding hypernatremia as a risk factor and grouping patients with serum sodiums below 130 and those with serum sodiums between 135 and 145 into a single group. Our experience suggests that such grouping would limit the predictive power of serum sodium as a risk factor.

- Additionally, several important laboratory predictors of severity that we have consistently found to have predictive power were not included in their clinical model. These include serum albumin, arterial pH, serum total bilirubin, and cardiac enzymes.

- In addition to the use of 30-day mortality as the outcome variable, some of the factors listed above may explain why the c-statistic for their clinical model (0.78) appears somwhat low to us for a model comparable to our physiologic full model.

- Despite the limitations cited above, the c-statistic for their physiologic model was substantially better than any of the administrative models evaluated, all of which had a c-statistic of 0.70. We wonder whether improved efforts to optimize the predictive power of their clinical data might have improved the c-statistic even further. Our physiologic full and lab models for heart failure have a c-statistic of 0.83 and 0.79, respectively.

- While these studies compared the predictive power of using an expanded claims dataset to a clinical dataset, based on our experience we question whether the selection and utilization of clinical variables, including laboratory results, was optimized.

- We continue to believe that the use of electronically captured laboratory results to obviate the risk of undesirable variability due to imprecise documentation and coding (see Section III) is likely to be more cost-effective than enhancing the claims dataset through intensive education or by constructing new, expanded alternative claims datasets.

o There are several studies that have evaluated the importance of including laboratory abnormalities on admission in any severity-stratification system, in order to achieve the necessary accuracy in estimating severity of illness on admission.

  - Pine et al (*Ann Int Med* 1997) and Iezzoni (*Ann Int Med* 1997) studied the risk-adjusted mortality using administrative data alone, administrative data plus laboratory results, and the combination of administrative data plus laboratory results plus clinical data.

    - Their results showed that, "*linking existing electronic data from laboratory reporting systems to administrative files could provide a cost-effective way to add valuable clinical information.*"

    - "*Additionally, even a few clinical variables can contribute substantially to predicting in-hospital deaths of general, acute care patients.*" Another study by Pine et al also resulted in similar findings (*International Journal for Quality in Health Care* 1998).

  - Sjauw et al studied the "Value of Routine Admission Laboratory Tests to Predict Thirty-Day Mortality in Patients with Acute Myocardial Infarction" (*Am J Cardiol* 2006). Their results showed that, "*In multivariate*

analyses, higher white blood cell count, higher levels of serum creatinine, glucose, and lactate dehydrogenase, and lower platelet count were identified as independent risk factors for 30-day mortality. The model that incorporated these risk factors (added laboratory parameters model) had a 17% higher predictive power than did the model that contained only conventional risk factors (conventional risk factor model)."

- They found that, "*The added laboratory parameters model showed better discriminative ability than the conventional risk factor model according to the area under the curve (0.87 vs 0.80).*" They concluded that, "*routine admission laboratory tests hold significant prognostic information, with value in addition to conventional risk factors.*"

- Freire et al studied the risk factors for mortality on admission in patients admitted to the medical intensive care unit (*CHEST* 2005). Their results showed that, "*APACHE II score/per point (odds ratio, 1.06), mechanical ventilation (odds ratio, 3.06), severe hypoalbuminemia (< 2 g/dL) [odds ratio, 2.98], and severe lactic acidemia (> 8 mmol/L) [odds ratio, 7.3] to be associated with hospital mortality.*"

- Fonarow et al (*JAMA* 2005) studied the risk factors for hospital mortality on admission in acute heart failure using objective physiologic data from a large acute heart failure registry (263 institutions nationwide). Of 39 variables that predicted hospital mortality the three variables that were the greatest predictors of mortality were BUN > 43 mg/dL, SCr > 2.75 mg/dL and systolic blood pressure < 115.

- Khuri et al (*J Am Coll Surg* 1997) studied the preoperative predictors of postoperative mortality in a Veterans Affairs Surgical Risk Study. When they tried to determine the importance of predictive values for post-operative mortality across all operators, six of the top 20 predictors were laboratory results: normal albumin (odds ratio (OR) = 0.57), BUN > 40 (OR = 1.49), platelets < 115K (OR = 1.76), SGOT/ALT > 40 IU/L (OR = 1.31), white blood cell count > 11K (OR = 1.35), and serum sodium $\leq$ 135 (OR = 1.32).

- In one of the few reports on use of electronically captured laboratory data to predict hospital mortality, Froom (*Clin Chem* 2006) did a study to, "*explore whether electronically retrieved laboratory data can predict mortality in internal medicine departments in a regional hospital.*" They found that, "*Nearly all patients had a complete blood count and basic clinical chemistries on admission.*"

  - Their results showed that, "*Eight laboratory variables and age significantly and independently contributed to a logistic regression model (area under the ROC curve, 88.7%).*"

  - They concluded that, "*A logistic regression model including only age and electronically retrieved laboratory data highly predicted mortality in internal medicine departments in a regional hospital, suggesting*

that age and routine admission laboratory tests might be used to ensure a fair comparison when using mortality monitoring for hospital quality control."

C. Section Conclusion:

- Inclusion of objective time-stamped results consistently produces risk-adjustment models with strong predictive power (c-statistics above 0.80).
- There are numerous examples drawn from the literature to support the use of laboratory values on admission to estimate admission-based severity.
- The use of laboratory values can minimize issues associated with identification of co-morbidities. For example, knowing that serum blood urea nitrogen and creatinine obviates the need to use ICD-9-CM codes as a measure of renal insufficiency.

IV. Selected Literature

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V. Appendix

Table 1. Misclassification of high-performance hospitals based on hospital level risk-adjusted mortality rates in common diseases estimated using claims, physiologic lab and physiologic full models.

[illegible]	Total [illegible]	In-Hospital [illegible]	Misclassification* of Performance (%)	
			[illegible]	[illegible]
CHF	210	4.0	38.1	40.5
AMI	201	7.4	45.0	50.0
Pneumonia	210	5.6	19.1	21.4
Respiratory Failure	173	18.9	42.9	34.3
Sepsis	180	18.4	30.6	36.1
Stroke	188	6.1	18.4	31.6
DM	195	1.2	7.7	7.7

CHF = heart failure; AMI = acute myocardial infarction; COPD = chronic obstructive pulmonary disease;
DM = diabetes mellitus; PLM = physiologic laboratory model; PFM = physiologic full model;
* Defined as: Hospitals that are in the top two deciles of risk-adjusted mortality using claims models but not in the top two deciles by the physiologic model in the comparison.

Table 2. Sensitivity and specificity of claims data to detect common laboratory abnormalities* identified from 83 institutions that provide electronically captured laboratory results during hospitalization [refer to Tables 3-5 for raw data for each analysis described].

Laboratory Abnormality*	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
Low Serum Sodium (≤ 135 mEq/L)	9.7	99.8	95.0	72.5
High Serum Sodium (> 145 mEq/L)	9.8	99.9	85.0	96.1
Low Serum Potassium (< 3.5 mEq/L)	18.6	99.3	85.9	83.7
High Serum Potassium (> 5.0 mEq/L)	15.0	99.7	87.4	90.7
Low Serum Hemoglobin (< 12 g/dl for females, < 14 for males g/dl)	9.1	99.3	96.1	35.8

* Using Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15^{nth} Edition, 2001.
ICD-9 Codes used: Low serum sodium (271.61), high serum sodium (276.0), low serum potassium (276.8), high serum potassium (276.7), low serum hemoglobin (285.9).

Figure 1 (a, b and c). Comparison of hospital-level rank based on risk-adjusted mortality rate with claims, physiologic lab (PLM), or physiologic full model (PFM) for heart failure.

Figure 1a. Claims model vs. physiologic lab model

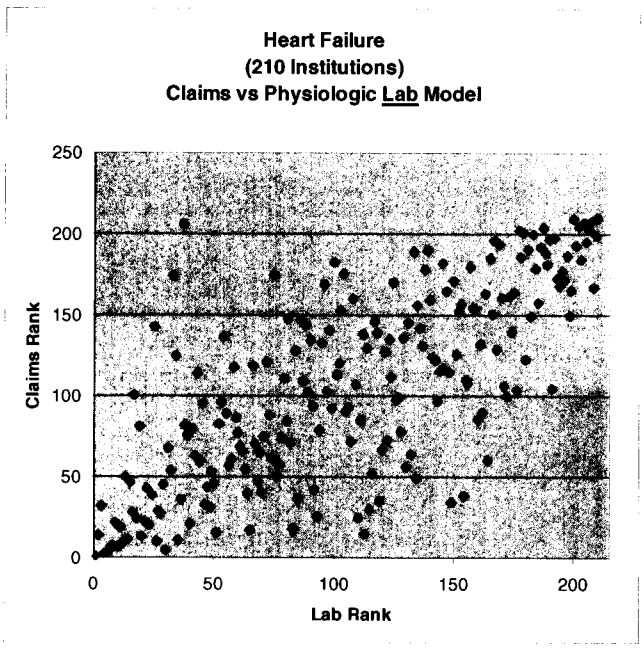


Figure 1b. Claims vs. physiologic full model

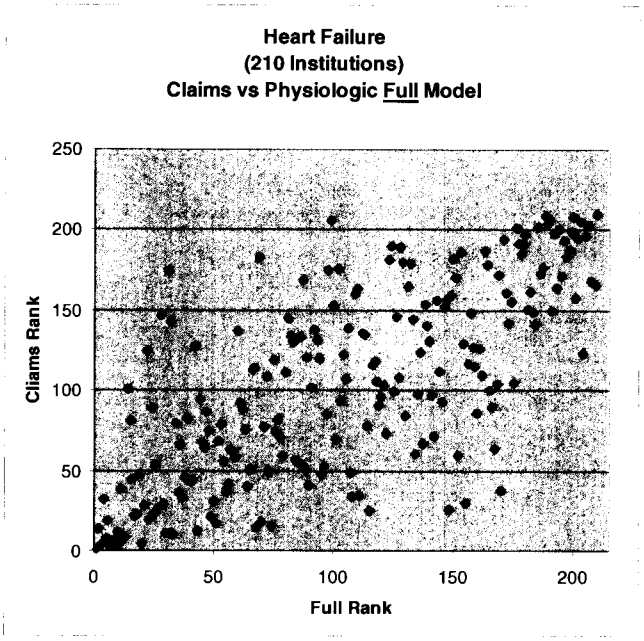
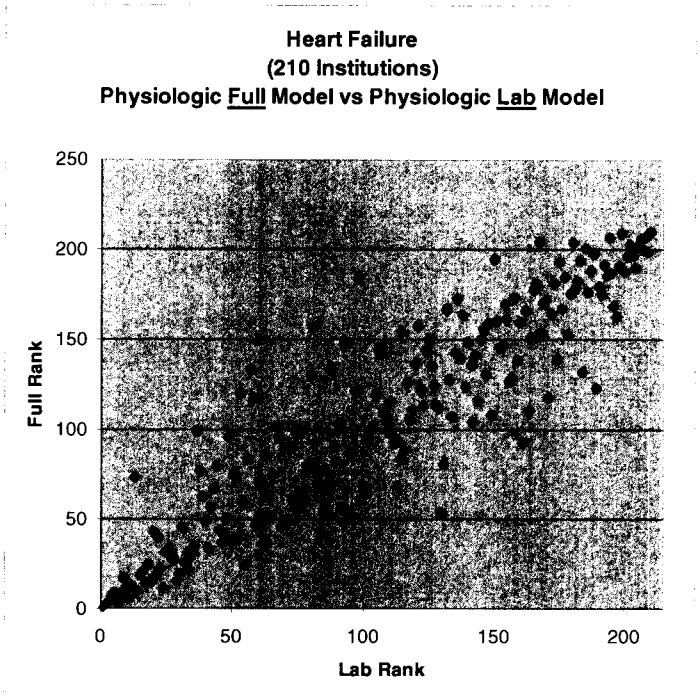


Figure 1c. Physiologic full model vs. physiologic lab model



Summary of Results: The agreement between PLM and PFM is much higher (less scattered) than that of claims model (more scattered) and either PLM or PFM models.

Figure 2 (a, b and c). Comparison of hospital-level rank based on risk-adjusted mortality rate with claims, physiologic lab (PLM), or physiologic full model (PFM) for acute myocardial infarction (AMI).

Figure 2a. Claims vs. physiologic lab model

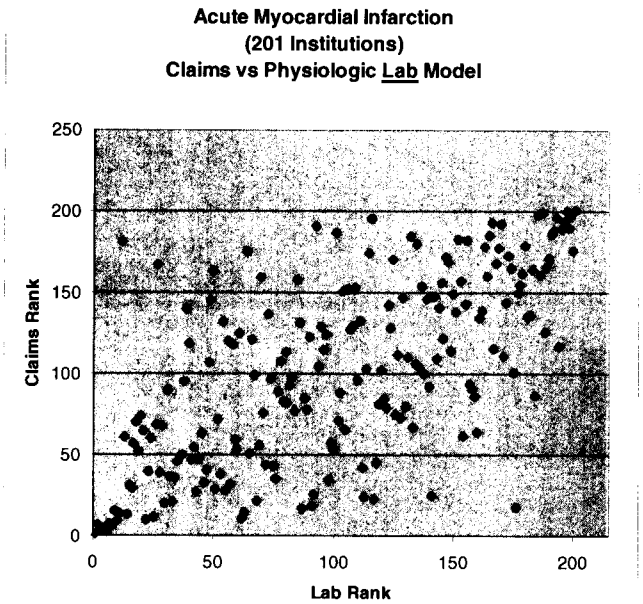


Figure 2b. Claims vs. physiologic full model

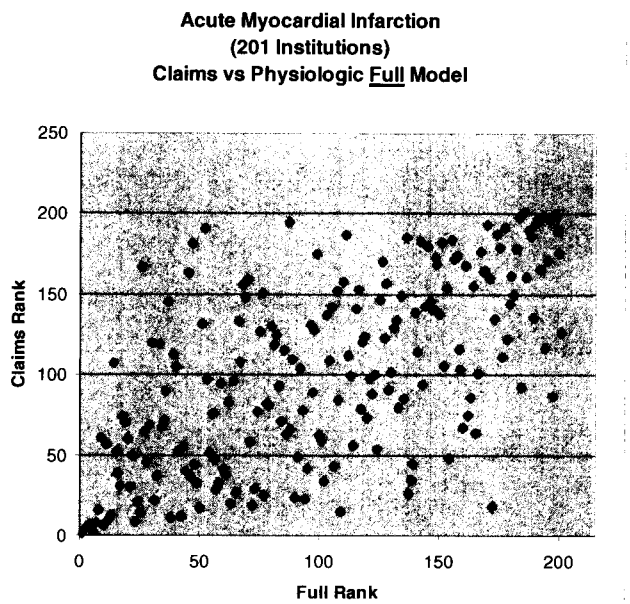
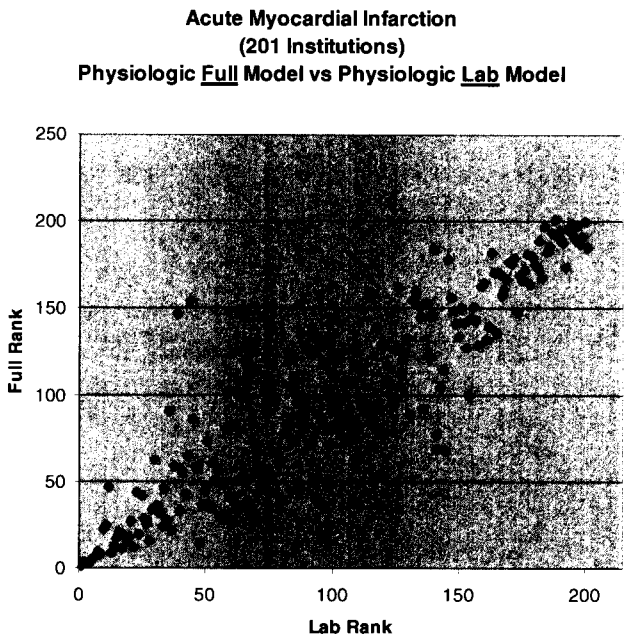


Figure 2c. Physiologic full model vs. physiologic lab model.



Summary of Results: The agreement between PLM and PFM is much higher (less scattered) than that of claims model (more scattered) and either PLM or PFM models.

Figure 3 (a, b and c). Comparison of hospital-level rank based on risk-adjusted mortality rate with claims, physiologic lab (PLM), or physiologic full model (PFM) for pneumonia.

Figure 3a. Claims vs. physiologic lab model

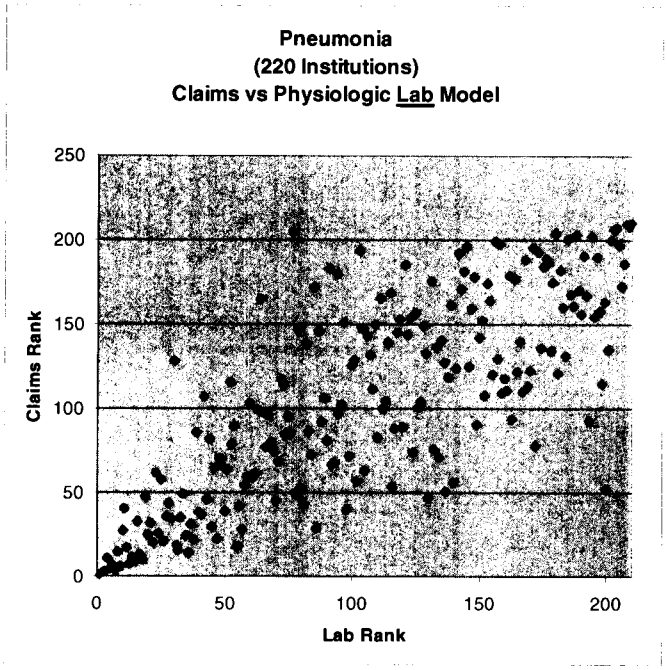


Figure 3b. Claims vs. physiologic full model

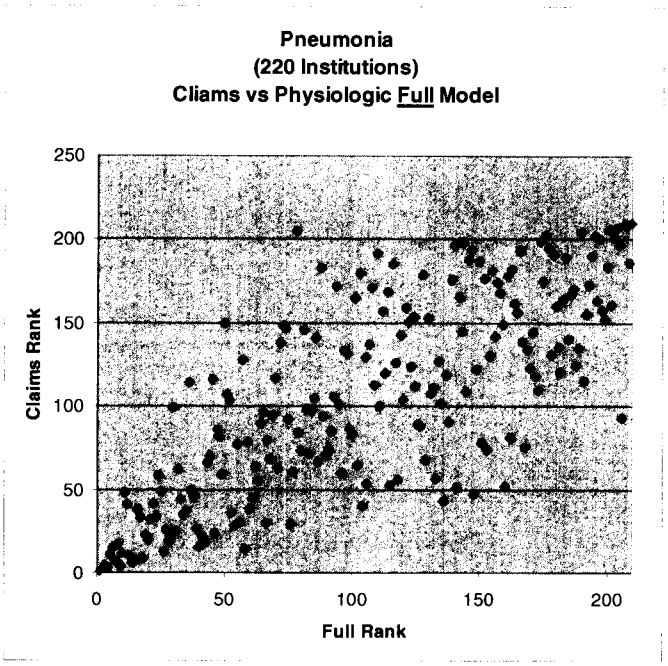
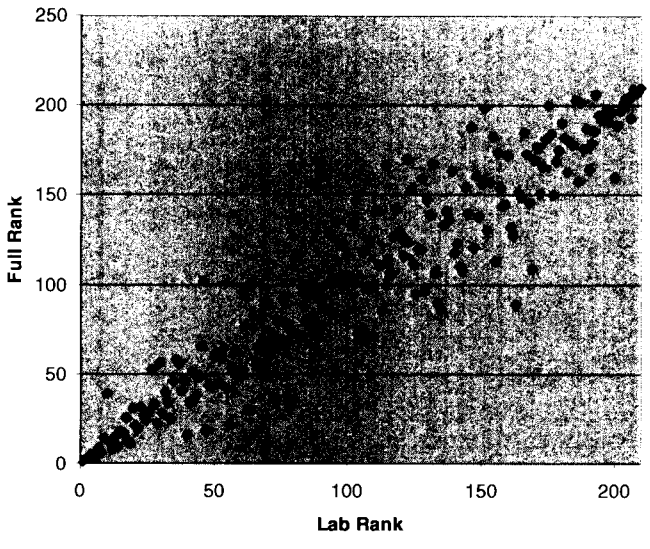


Figure 3c. Physiologic full model vs. physiologic lab model



Summary of Results: The agreement between PLM and PFM is much higher (less scattered) than that of claims model (more scattered) and either PLM or PFM models.

Figure 4 (a, b and c). Comparison of hospital-level rank based on risk-adjusted mortality rate with claims, physiologic lab (PLM), or physiologic full model (PFM) for respiraotry failure.

Figure 4a. Claims vs. physiologic lab model

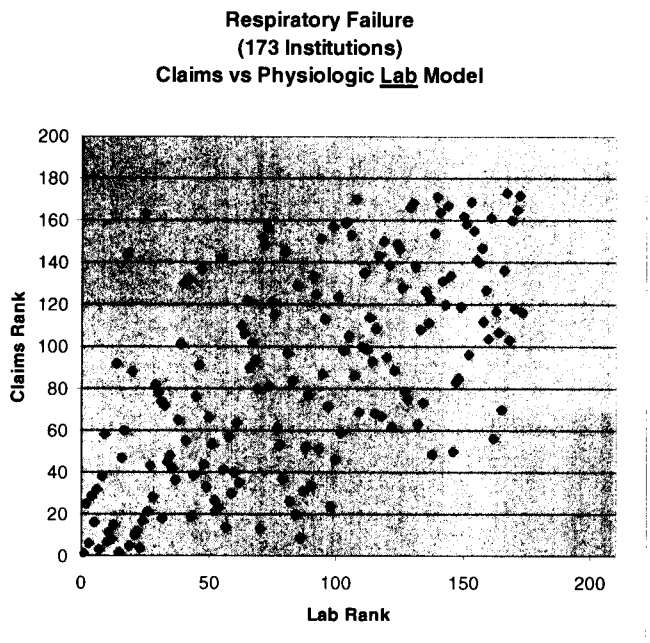


Figure 4b. Claims vs. physiologic full model

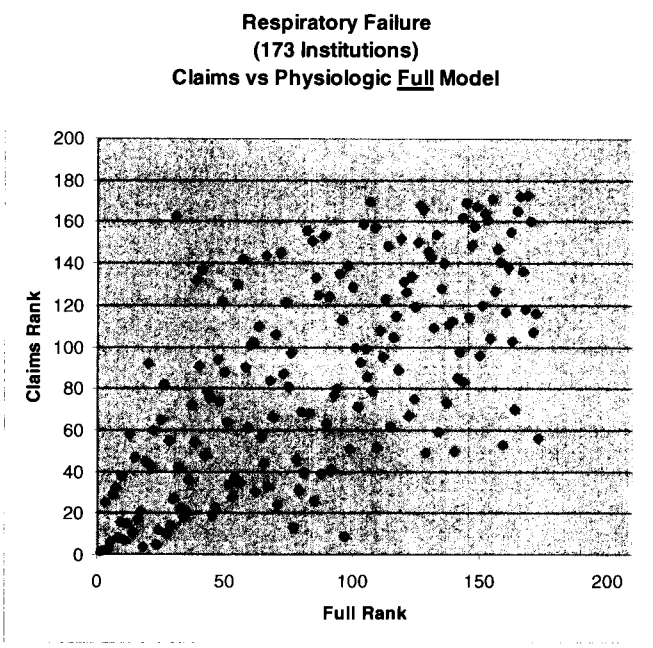
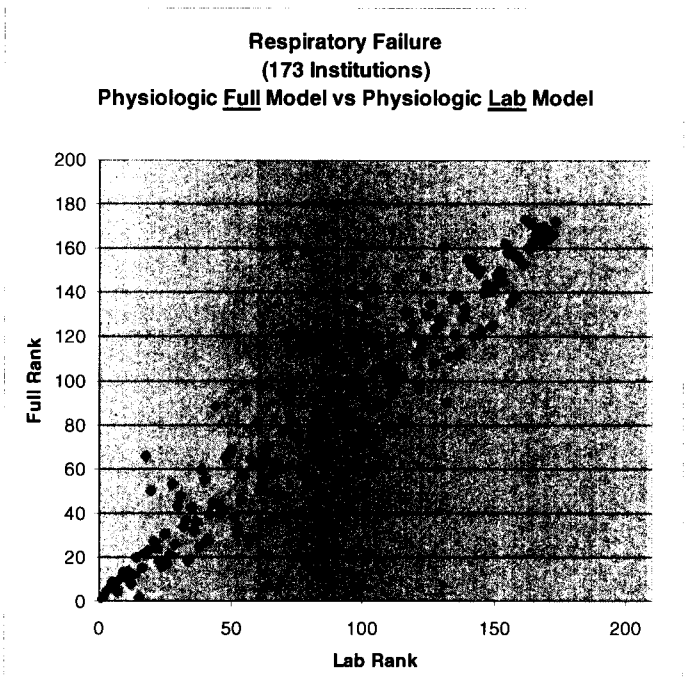


Figure 4c. Physiologic full model vs. physiologic lab model



Summary of Results: The agreement between PLM and PFM is much higher (less scattered) than that of claims model (more scattered) and either PLM or PFM models.

Figure 5 (a, b and c). Comparison of hospital-level rank based on risk-adjusted mortality rate with claims, physiologic lab (PLM), or physiologic full model (PFM) for sepsis.

Figure 5a. Claims vs. physiologic lab model

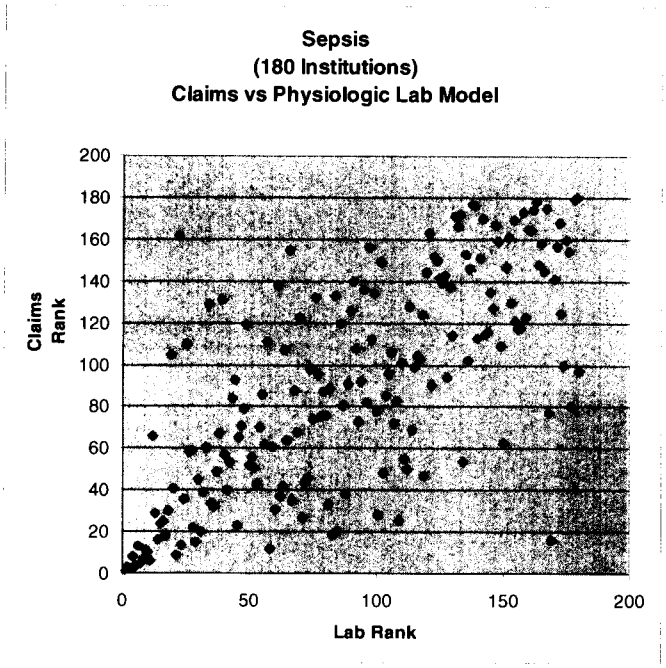


Figure 5b. Claims vs. physiologic full model

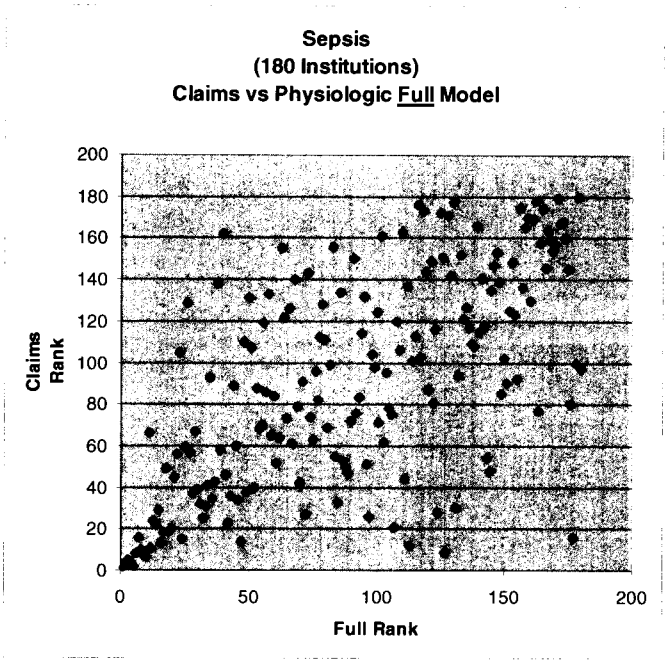
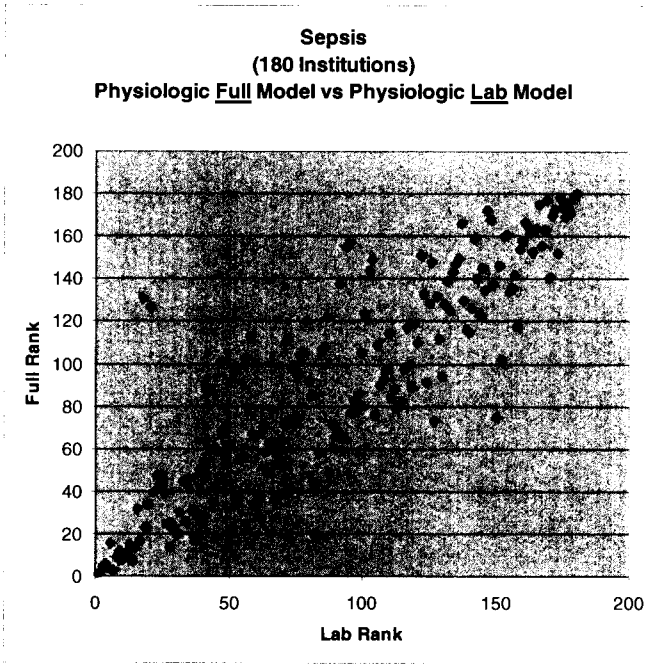


Figure 5c. Physiologic full model vs. physiologic lab model.



Summary of Results: The agreement between PLM and PFM is much higher (less scattered) than that of claims model (more scattered) and either PLM or PFM models.

Figure 6 (a, b and c). Comparison of hospital-level rank based on risk-adjusted mortality rate with claims, physiologic lab (PLM), or physiologic full model (PFM) for stroke.

Figure 6a. Claims vs. physiologic lab model

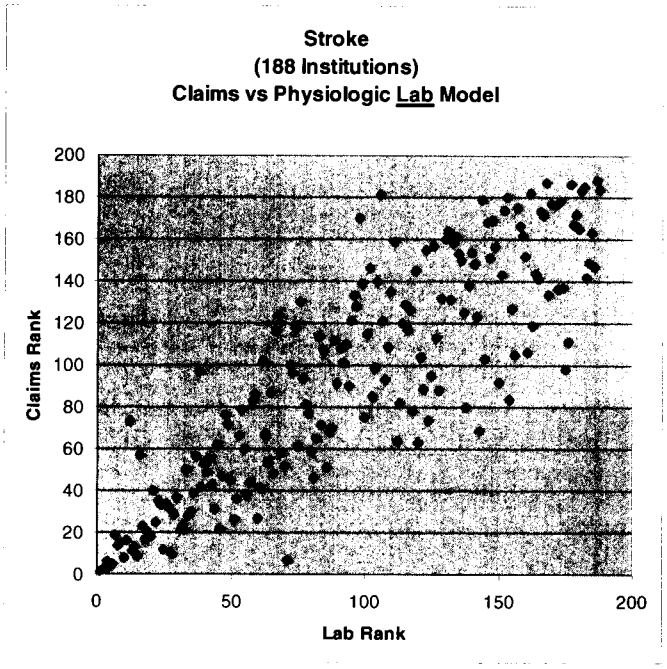


Figure 6b. Claims vs. physiologic full model

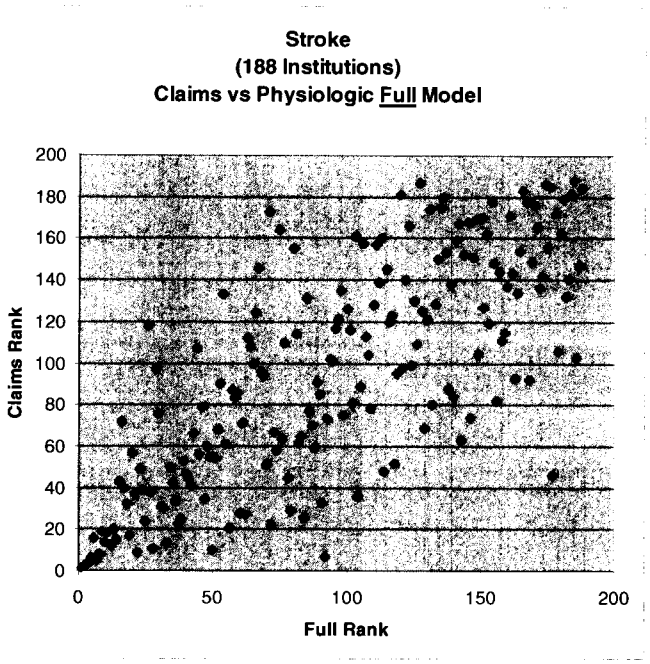
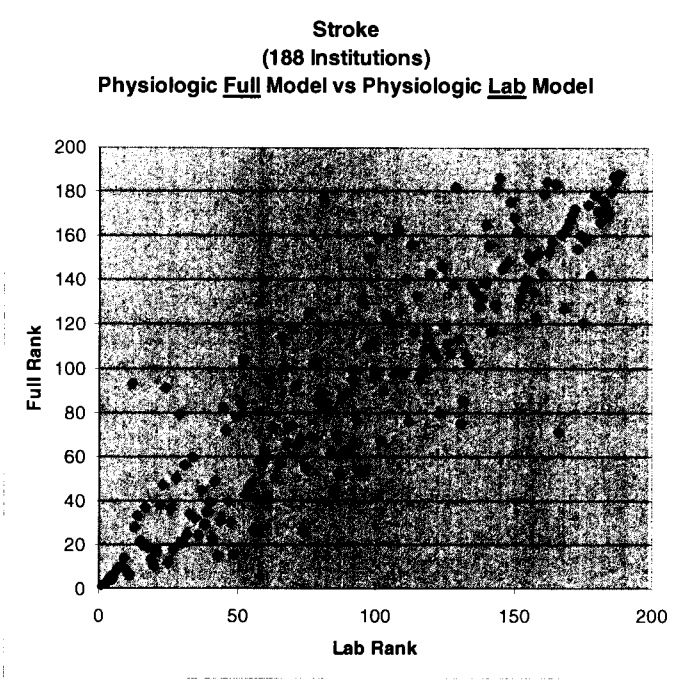


Figure 6c. Physiologic full model vs. physiologic lab model.



Summary of Results: The agreement between PLM and PFM is much higher (less scattered) than that of claims model (more scattered) and either PLM or PFM models.

Figure 7 (a, b and c). Comparison of hospital-level rank based on risk-adjusted mortality rate with claims, physiologic lab (PLM), or physiologic full model (PFM) for diabetes.

Figure 7a. Claims vs. physiologic lab model

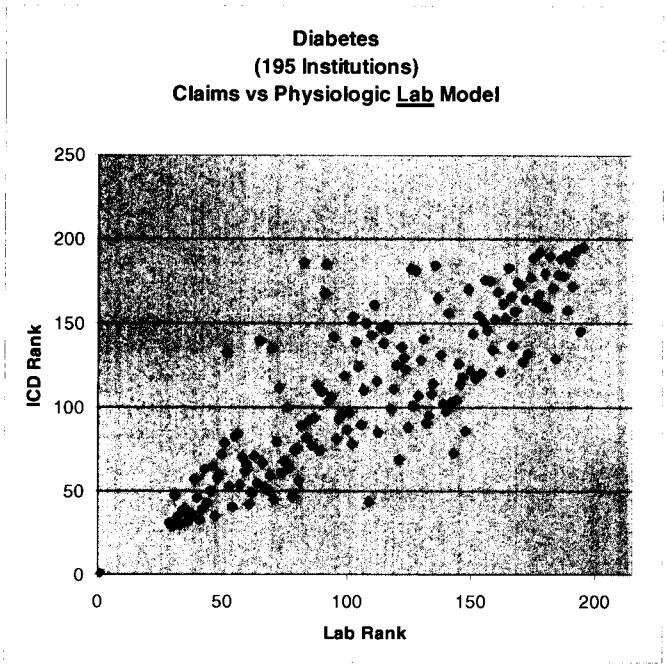


Figure 7b. Claims vs. physiologic full model

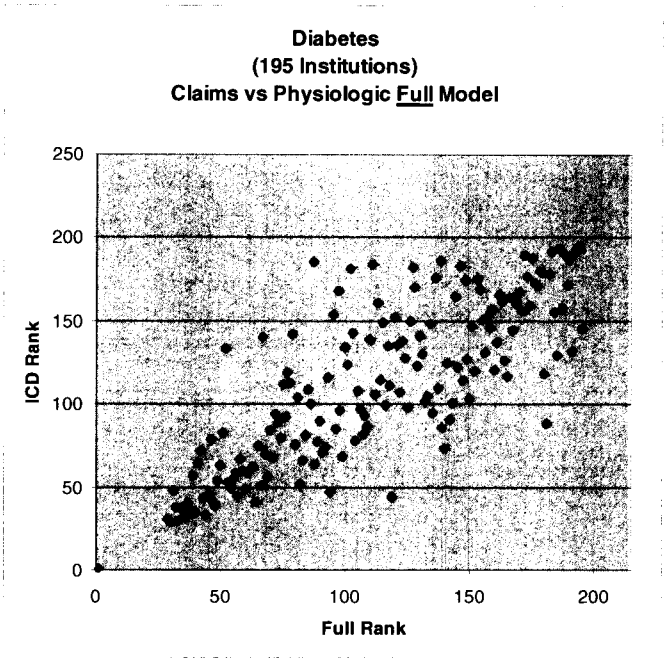
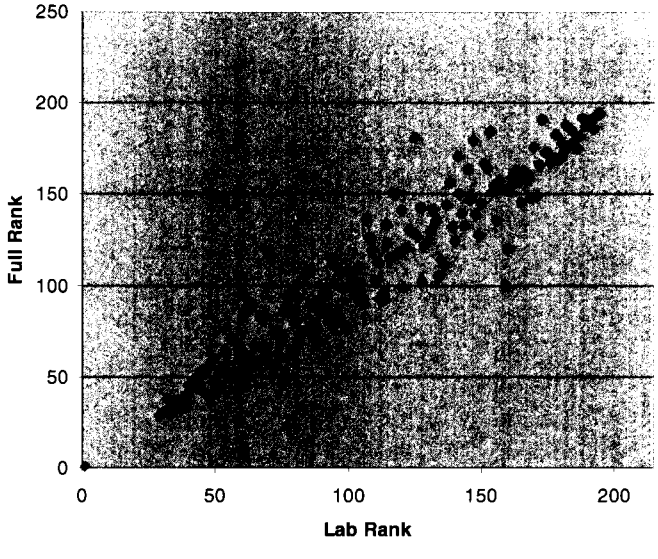


Figure 7c. Physiologic full model vs. physiologic lab model



Summary of Results: The agreement between PLM and PFM is much higher (less scattered) than that of claims model (more scattered) and either PLM or PFM models.

Table 3 (a and b). Two by two table of the ability of claims data to detect serum sodium abnormalities identified from 83 institutions that provide electronically captured laboratory results during hospitalization [see figure 8 for in-hospital mortality by serum sodium result].

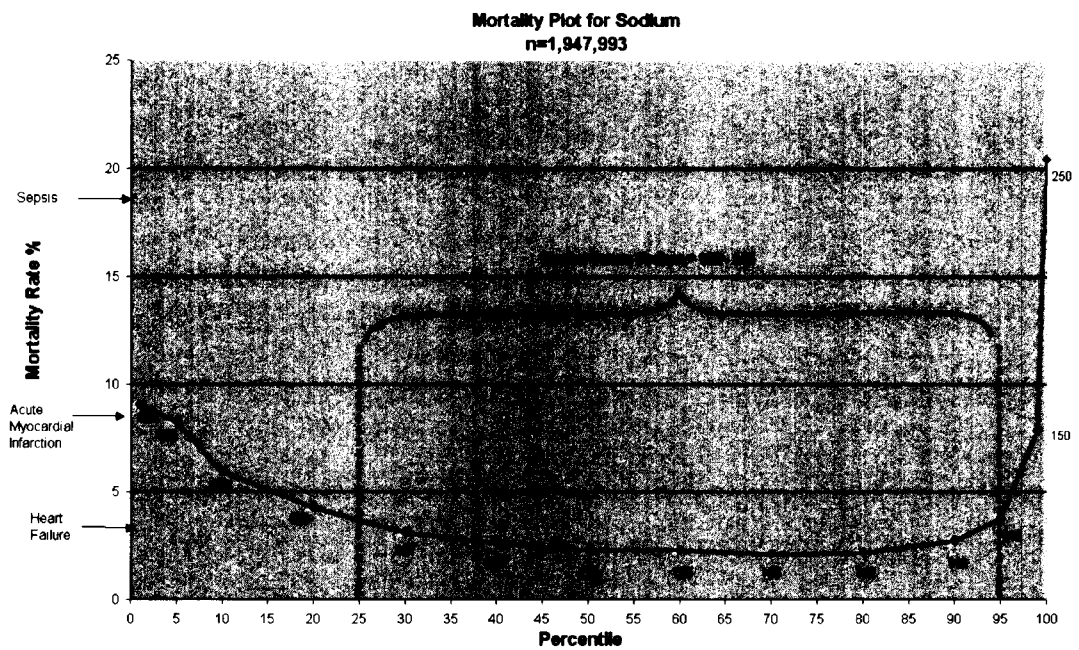
Table 3a. Low serum sodium.

ICD9 Code Present (276.1)	Low Serum Sodium (< 135 mEq/L) Yes	No		
Yes	16,612	880	95.0%	PPV
No	154,331	407,055	72.5%	NPV
	9.7% Sensitivity	99.8% Specificity		

Table 3b. High serum sodium.

ICD9 Code Present (276.0)	High Serum Sodium (> 145 mEq/L) Yes	No		
Yes	2,484	440	85.0%	PPV
No	22,763	553,191	96.0%	NPV
	9.8% Sensitivity	99.9% Specificity		

Figure 8. In-hospital mortality by serum sodium value from institutions that provide electronically captured laboratory results during hospitalization [corresponds to figure 2 in text].



Note: Each plot point provides mortality at the serum sodium result (normal as per Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15nth Edition, 2001). As mortality rate varies by disease group, the arrows adjacent to the y-axis indicate the hospital mortality for sepsis, acute myocardial infarction and heart failure.

Table 4 (a and b). Two by two table of the ability of claims data to detect serum potassium abnormalities identified from 83 institutions that provide electronically captured laboratory results during hospitalization [see Figure 9 for in-hospital by serum potassium result].

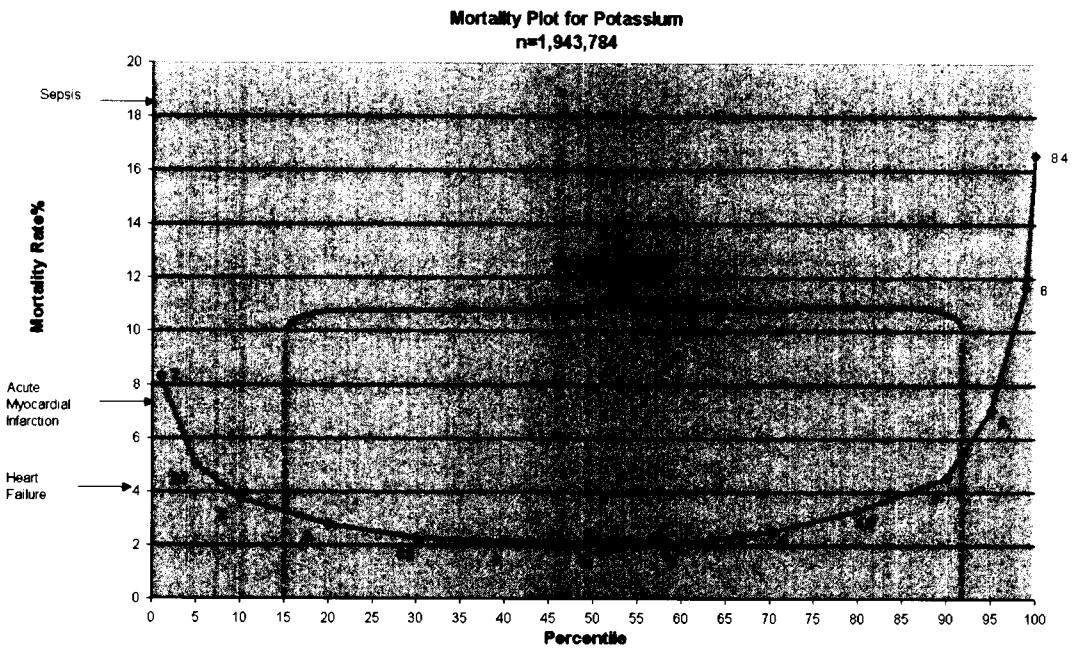
Table 4a. Low serum potassium.

ICD9 Code Present (276.8)	Low Serum Potassium (< 3.5) Yes	No		
Yes	20,693	3,393	85.9%	PPV
No	90,699	464,093	83.7%	NPV
	18.6% Sensitivity	99.3% Specificity		

Table 4b. High serum potassium.

ICD Code Present (276.7)	High Serum Potassium (> 5.0) Yes	No		
Yes	9344	1347	87.4%	PPV
No	53087	515100	90.7%	NPV
	15.0% Sensitivity	99.7% Specificity		

Figure 9. In-hospital mortality by serum potassium value from institutions that provide electronically captured laboratory results during hospitalization.

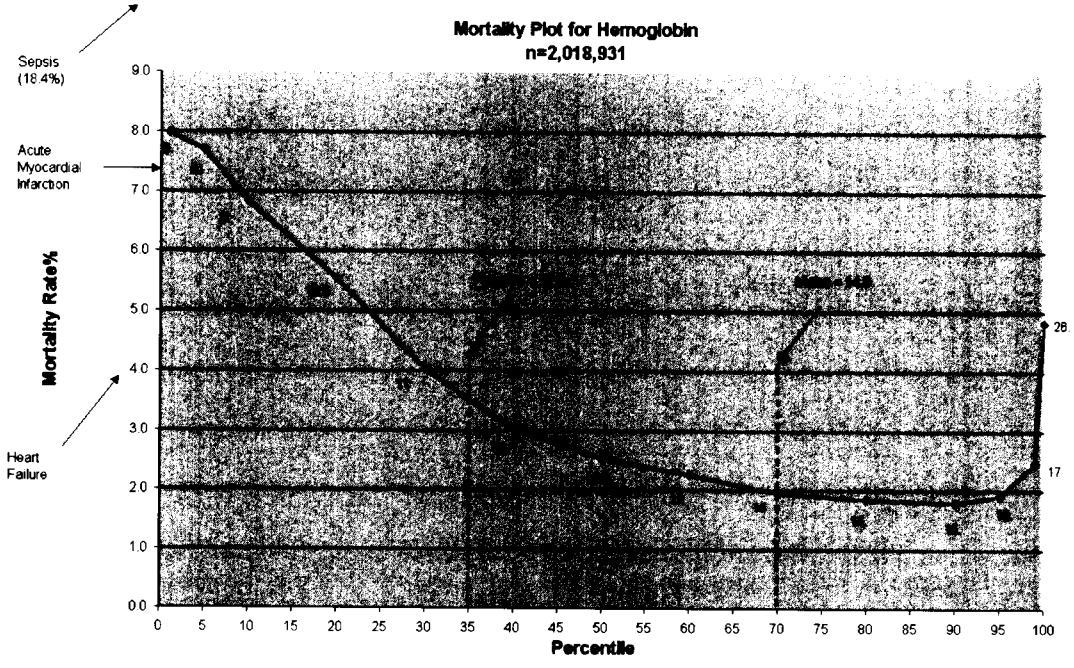


Note: Each plot point provides mortality at the serum potassium result (normal as per Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15nth Edition, 2001). As mortality rate varies by disease group, the arrows adjacent to the y-axis indicate the hospital mortality for sepsis, acute myocardial infarction, and heart failure.

Table 5. Two by two table of the ability of claims data to detect low serum hemoglobin abnormality (anemia) identified from 83 institutions that provide electronically captured laboratory results during hospitalization [see figure 10 for in-hospital by serum hemoglobin result].

ICD Code Present (285.9)	Low Serum Hemoglobin (anemia) (< 12 mg/dl for females or < 14 for males			
	Yes	No		
Yes	34693	1422	96.1%	PPV
No	348782	193981	35.7%	NPV
	9.0% Sensitivity	99.3% Specificity		

Figure 10. In-hospital mortality by serum hemoglobin value from institutions that provide electronically captured laboratory results during hospitalization.



Note: Each plot point provides mortality at the serum hemoglobin result. Cutoff for normal serum hemoglobin result is < 12 g/dl for females and < 14 g/dl for males (Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15nth Edition, 2001). As mortality rate varies by disease group, the arrows adjacent to the y-axis indicate the hospital mortality for sepsis, acute myocardial infarction, and heart failure.

Table 6. Sensitivity and improvement of claims data to detect common laboratory abnormalities* identified on admission from 83 institutions that provide electronically captured laboratory results [corresponds to table 3 in text].

Laboratory Abnormality	Sensitivity Admission Period	% Improvement from Full Hospital Stay
Low serum sodium (< 135 mEq/L)	11.8	2.1
High serum sodium (> 145 mEq/L)	12.3	2.5
Low serum potassium (< 3.5 mEq/L)	22.8	4.2
High serum potassium (> 5.0 mEq/L)	18.9	3.9
Low serum hemoglobin (< 12 g/dl for females, < 14 for males g/dl)	9.6	0.6

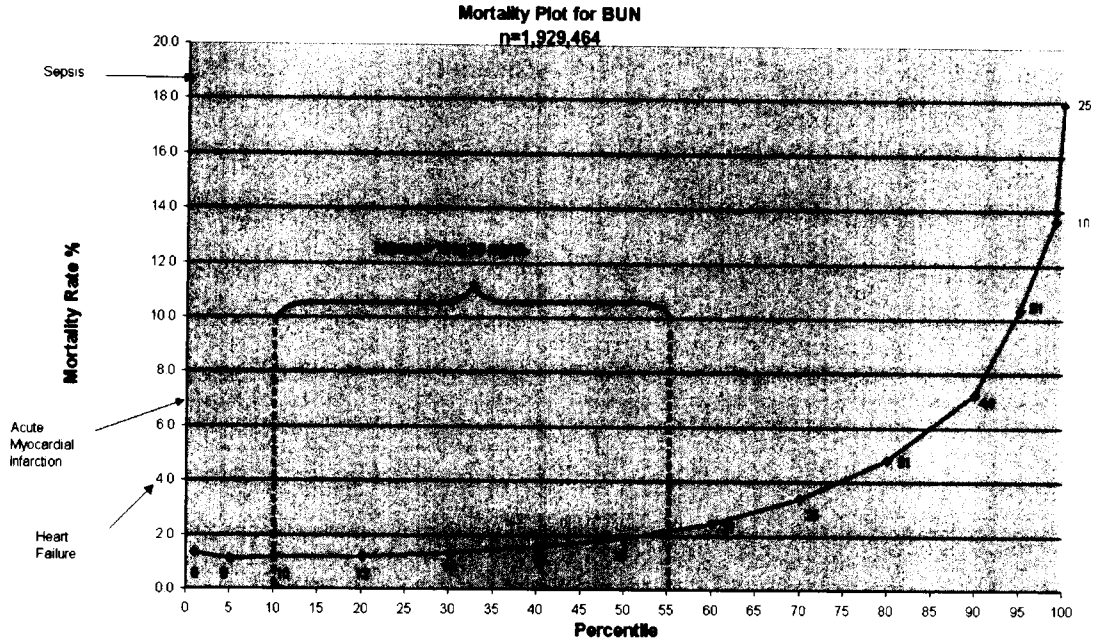
* Using Harrison's Principles of Internal Medicine. McGraw-Hill Professional; 15nth Edition, 2001.
ICD-9 Codes used: Low serum sodium (271.61), high serum sodium (276.0), low serum potassium (276.8), high serum potassium (276.7), low serum hemoglobin (285.9).

Table 7. Sensitivity of claims data to detect common laboratory abnormalities* identified more than 10 times during the hospitalization from 83 institutions that provide electronically captured laboratory results [corresponds to table 4 in text].

Laboratory Abnormality	Sensitivity of Claims Data (%)
Low serum sodium recorded >10 times (≤ 135 meq/L)	30.0
High serum sodium recorded >10 times (>145 meq/L)	42.2
Low serum potassium recorded >10 times (< 3.5 meq/L)	19.5
High serum potassium recorded >10 times (> 5.0 meq/L)	20.4
Low serum hemoglobin Hgb recorded >10 times (<12 g/L for females or <14 g/L for males)	9.5

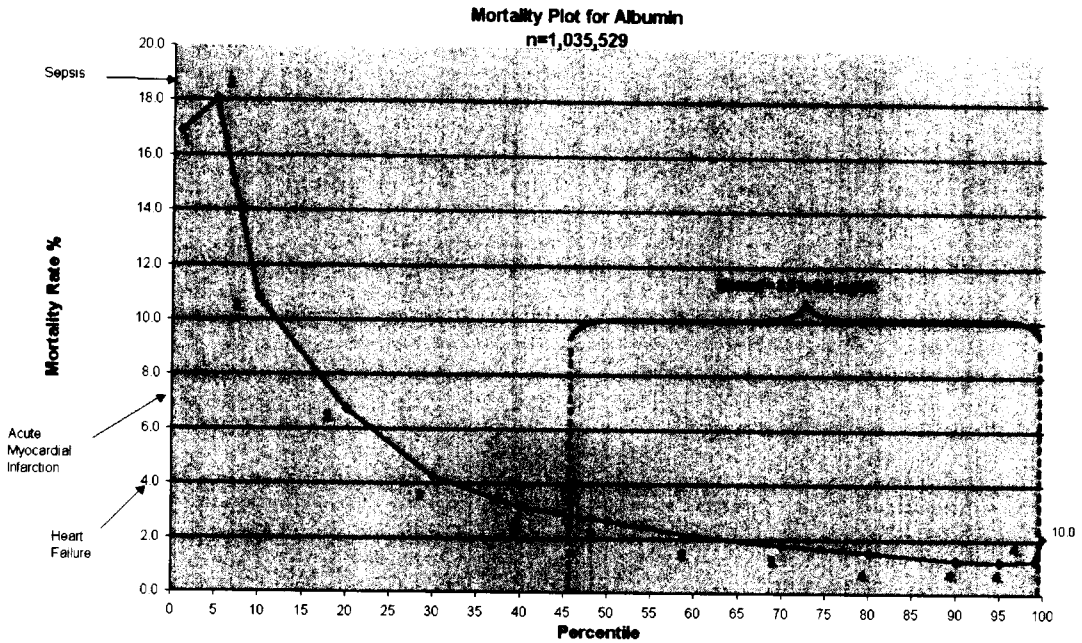
* Using Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15nth Edition, 2001.
ICD-9 Codes used: Low serum sodium (271.61), high serum sodium (276.0), low serum potassium (276.8), high serum potassium (276.7), low serum hemoglobin (285.9).

Figure 11. In-hospital mortality by serum blood urea nitrogen (BUN) value from institutions that provide electronically captured laboratory results during hospitalization.



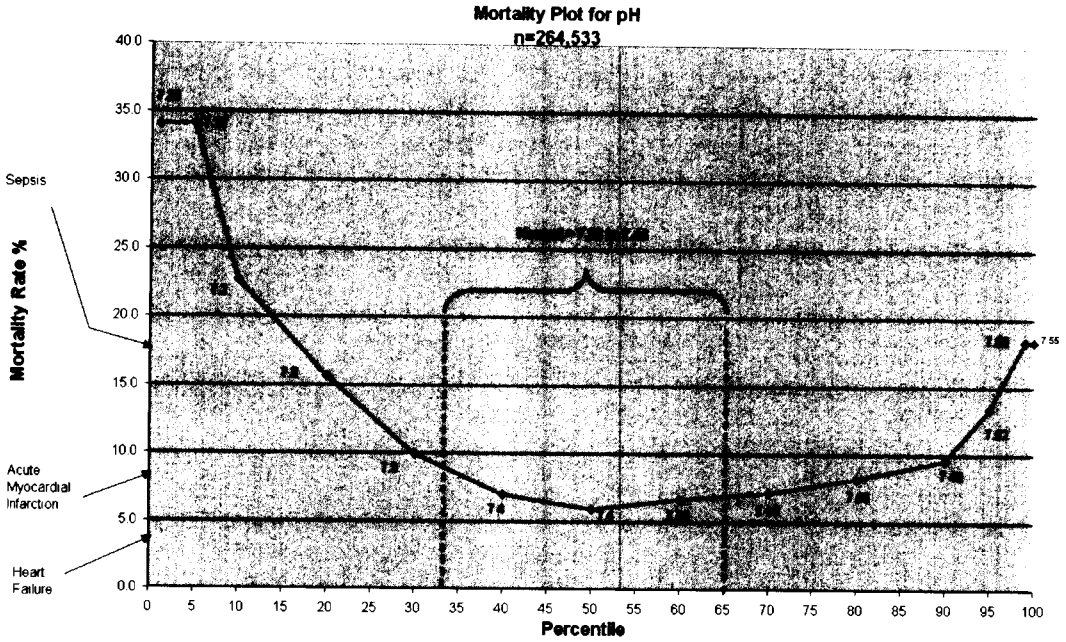
Note: Each plot point provides mortality at the serum blood urea nitrogen (BUN) result (normal as per Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15^{nth} Edition, 2001). As mortality rate varies by disease group, the arrows adjacent to the y-axis indicate the hospital mortality for sepsis, acute myocardial infarction, and heart failure.

Figure 12. In-hospital mortality by serum albumin value from institutions that provide electronically captured laboratory results during hospitalization.



Note: Each plot point provides mortality at the serum albumin result (normal as per Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15^{nth} Edition, 2001). As mortality rate varies by disease group, the arrows adjacent to the y-axis indicate the hospital mortality for sepsis, acute myocardial infarction, and heart failure.

Figure 12. In-hospital mortality by serum pH value from institutions that provide electronically captured laboratory results during hospitalization.



Note: Each plot point provides mortality at the serum pH result (normal as per Harrison's Principles of Internal Medicine. McGraw-Hill Professional, 15nth Edition, 2001). As mortality rate varies by disease group, the arrows adjacent to the y-axis indicate the hospital mortality for sepsis, acute myocardial infarction, and heart failure.

157

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June 12, 2006

BY HAND DELIVERY

Honorable Mark B. McClellan, M.D., Ph.D.
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Re: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of the 1,400 leading not-for-profit hospitals and health systems allied in Premier, I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the FY'07 Medicare Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 *Federal Register*. Premier is a strategic alliance of approximately 200 independent, not-for-profit health systems that operate or are affiliated with more than 1,400 hospitals and healthcare sites nationwide. Our comments primarily reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in the effective operation of the IPPS.

DRG CHANGES

Given the complexities of CMS' proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on our member hospitals and on all hospitals in the country, we strongly urge a one-year delay in implementing these policy proposals. More time is needed to review these complex proposals and to offer viable alternatives to the proposed changes discussed in the *Federal Register*.

CMS proposes to move from the historical charge-based DRG system to a cost-based system and to implement hospital-specific relative weights by October 1, 2006. CMS also proposes modifying the DRG classification system to account for differences in patient severity and allow for a payment amount that more closely tracks the cost of providing

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care. In its proposal, CMS states that it would replace the current 526 DRGs with either the proposed 861 consolidated severity-adjusted DRGs by FY'08 or a similar system that accounts for the level of patient severity, developed in response to public comments that it receives.

The magnitude of these changes cannot be minimized. CMS would re-distribute about $1.5 billion in Medicare payments across U.S. hospitals. Many of the hospitals that would lose revenues are among the leading institutions in the country, providing the best care available today as well as leading innovation to improve future healthcare.

Premier supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a DRG system that more accurately reflects the costs of providing inpatient services. We wholeheartedly support your initiative to make payments more accurate and fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. We have several serious concerns and comments, however, with the CMS proposal for calculating DRG weights and the proposed modifications to the DRG classification system.

Methodological Concerns

- CMS does not follow the cost-based methodology recommended by the Medicare Payment Advisory Commission (MedPAC) or the methodology used to calculate cost-based weights in the outpatient prospective payment system. Instead, CMS proposed a new and complex methodology which has not been tested or subjected to external review and analysis.

- The methodology proposed by CMS raises two very serious concerns. First, CMS trimmed the data in a crucial step of the calculation, with the result that hospitals representing 25 percent of total charges for routine care were thrown out even though they were retained in other parts of the calculation. Second, in computing national average cost-to-charge ratios, CMS did not weight by hospitals' volume of cases or charges. Not accounting for volume leads to a serious distortion of the national average.

- The proposed patient classification system incorporating severity adjustment needs refining for implementation and some details of the proposal were not available for review and comment. The grouping software should be made available so that hospitals can review how the proposed changes would affect their caseload, but this was not done apparently because the software is proprietary. We strongly believe that the grouping sofware used by Medicare should be in the public domain.

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- Because of the methodological concerns and the unavailability of the severity DRG grouper, hospitals and the public have not had the opportunity to review the proposals adequately and assess their financial impact. The table below illustrates our concerns regarding the methodology and the impact it would have on selected types of hospitals and selected DRGs.

IMPACT OF HSRVcc ON HOSPITALS, BY TYPE		CMS	Corrected
	Urban (2,517)	-0.5%	-0.3%
	Large Urban (1,391)	-0.2%	-0.2%
	Other Urban (1,126)	-1.0%	-0.5%
	Urban, At Least 300 Beds (580)	-1.4% to -2.1%	-0.8% to -1.2%
	Rural (1,005)	+3.0%	+1.6%
	Major Teaching (237)	-1.5%	-0.9%
	Specialty Cardiac (54)	-10.4%	-5.8%
	Specialty Orthopedic (73)	-3.3%	+2.9%
	Specialty Surgical (151)	-3.6%	-1.6%
IMPACT ON SELECTED DRGs OF HSRVcc		**CMS**	**Corrected**
558	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W/O Maj Cv Dx	-35%	-21%
557	Percutaneous Cardiovascular Proc W Drug-Eluting Stent W Major Cv Dx	-26%	-15%
125	Circulatory Disorders Except Ami, W Card Cath W/O Complex Diag	-28%	-20%
124	Circulatory Disorders Except Ami, W Card Cath & Complex Diag	-19%	-14%
535	Cardiac Defib Implant W Cardiac Cath W Ami/Hf/Shock	-26%	-16%
536	Cardiac Defib Implant W Cardiac Cath W/O Ami/Hf/Shock	-25%	-13%

Weight Calculation Methodology

- Premier supports a change from charge-based to cost-based weights accompanied by specific actions to address known limitations in the accuracy of the Medicare cost report data. Two shortcomings are particularly important. First is the problem of charge compression. To determine the cost of individual items and services, CMS generally takes hospitals' charges for an individual item or service and converts them to an estimated cost. Specifically, CMS converts charges to costs by "backing out" the *average*

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mark-up calculated for each department. Thus, if a department had an average mark-up in which charges averaged twice the department's costs, then a charge of $1,000 would be reduced to a cost of $500 after adjusting for the mark-up.

Basing the estimate of the cost for each item and service on the average mark-up in a particular department implicitly assumes that hospitals apply the same percentage mark-up to set the charge level of each item in the department. Many experts and studies have noted, however, that hospitals generally do not apply a uniform percentage mark-up and that, in fact, the percentage mark-up for high cost items is less than the one used for lower cost items. According to a study commissioned by MedPAC, hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock". This phenomenon is called charge compression. To the extent that charge compression is present, the current CMS rate-setting methodology underestimates the cost of more expensive items and over-estimates the cost of less expensive ones, resulting in a systematic distortion of prospective payment rates. Premier strongly believes that changing to cost-based weights must address the distortion caused by charge compression.

- The other major issue with cost report information is the accuracy of the estimates of routine and ancillary costs. Studies comparing cost report information with information from sophisticated hospital accounting systems raise questions about the accuracy of the cost report data. An earlier ProPAC study, for example, found that the cost report overstated routine costs by more than 12 percent and understated ancillary costs by nearly 5 percent. This significant issue should be addressed as CMS implements cost-based weights. A one-year delay will provide the time needed to make improvements in the cost report system.

- Premier questions the accuracy of the hospital relative value (HSRV) method. We believe that accurately determined cost-based weights are the gold standard and that HSRV, distorts the cost-based weights. We note that cardiac surgery and cardiology services, especially interventional cardiology services, are performed primarily in the type of hospitals that are disadvantaged by the HSRV methodology. The weights for these services are disadvantaged by HSRV even though the hospitals performing them tend to mark up their charges for these services less than they mark up their charges for other services. In fact hospitals losing under HSRV have lower charges for these cardiac services than do hospitals which win under HSRV. HSRV disadvantages cardiac services because hospitals performing the preponderance of these services tend to charge more than average for typical

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cases, therefore their charges for the very expensive cardiac cases are down-weighted in calculating the HSRV weights. In addition, cardiac services tend to be higher weighted services and thus are disadvantaged by the compression of the DRG weights that is a hallmark of the HSRV methodology.

Consolidated Severity-Adjusted DRGs

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In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG (CS-DRG) model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals. We especially note that numerous recent changes to improve the DRG classification of particular types of cases are not carried over to CS-DRGs. **We also note that case complexity, a significant factor in driving hospital resources, is not considered by the CS-DRG approach proposed by CMS. Page 24014 of the *Federal Register* notes that CMS will develop a plan to address this issue. We believe this should be addressed before implementation vs. after.** Hospitals need to know how resource use will effect payments. Also, we oppose a "behavioral" offset which will reduce payments even further before implementation of the consolidated severity-adjusted DRG and note that CMS should release details of any behavioral offset in any case.

Given the number and magnitude of issues in the proposed changes in DRG classification and weight calculation, Premier strongly urges CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY'08. The additional time will allow hospitals to more thoroughly evaluate the proposals and offer constructive feedback to your agency.

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NEW TECHNOLOGY

Section 503 of the MMA provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. However, CMS continues to resist approval of new technologies and considers only a few technologies a year for add-on payments. **Premier also is disappointed that CMS has not increased the marginal payment rate to 80 percent rather than 50 percent, consistent with the outlier payment methodology, as we have previously requested.**

We also are concerned about CMS' ability to implement add-on payments for new services and technologies in the near future or to make appropriate DRG classifications for new technologies. Unique procedure codes must be created and assigned to recognize new technologies and the ICD-9-CM classification system is close to exhausting codes to identify new health technologies. The ICD-9 system is in critical need of upgrading.

Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to as ICD-10) were developed as replacement classification systems.

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the MMA, recommended that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology, as required under the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000.

To date, despite these recommendations, as well as the recommendations of several federal healthcare agencies and offices and health care trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that absent a switch to ICD-10 soon, there will be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. In addition, failure to recognize this looming problem will only impede the efforts to achieve President Bush's goal for an electronic health record by 2014.

At the April 2005 ICD-9-CM Coordination and Maintenance (C&M) committee meeting, there were many impassioned discussions on the need to start limiting the

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creation of new procedure codes in order to allow the classification system to last at least two more years. ICD-9-CM procedure code categories 00 and 17 were created to capture a diverse group of procedures and interventions affecting all body systems. The establishment of these code categories represented a deviation from the normal structure of ICD-9-CM and a stopgap measure to accommodate new technology when no other slots in the corresponding body system chapters (e.g. musculosketal system, circulatory system, etc.) were available. The plan was to use codes in category 00 first and then begin populating chapter 17.

Category 00 is now full, and the C&M committee is entertaining proposals for codes in category 17. At the April C&M meeting a proposal was presented that would in effect leave only 80 codes available in this category. Many of the specific body system chapters are already filled (e.g., cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in one-and-a-half years. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule.

Thus, Premier strongly recommends that the Secretary undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS expeditiously. HHS should take the necessary steps to avert this crisis and avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than respond to a crisis that will likely result in unreasonable implementation timeframes. **It is imperative that the rulemaking process start immediately.**

Additional Payment for New Technologies

Premier supports CMS' proposal to continue to make new technology add-on payments for Endovascular Graft Repair of the Thoracic Aorta and for the Restore® Rechargeable Implantable Neurostimulator. We also urge CMS to approve new technology add-on payments for NovoSeven® for Intracerebral Hemorrhage. The technology is a drug that promotes hemostasis by activating clotting factors. Because the technology is not currently FDA approved, in the proposed rule CMS does not present an analysis on whether the technology meets the criteria for the new technology add-on payment in this proposed rule. However, CMS summarizes information submitted by the applicant on the cost and substantial clinical improvement criteria. Similar to the previous approval of Xigris, we believe that the availability of an add-on payment would help to facilitate patient access to this important and costly therapy.

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PROPOSED CHANGES TO DRG CLASSIFICATIONS

1. Carotid Artery Stents

Medicare covers percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Federal Drug Administration (FDA) approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials. Most cases of carotid artery stents are assigned to DRGs 533 (Extracranial Procedures with CC) and 534 (Extracranial Procedures without CC). **Premier supports the idea that all carotid stenting cases should be assigned to DRG 533 only, bypassing DRG 534 and we disagree with the CMS decision not to make this change.**

2. Insertion of Epicardial Leads for Defibrillator Devices

The ICD-9-CM Coordination and Maintenance Committee expanded the category of codes for defibrillators and pacemakers so that the codes for leads would no longer be restricted to pacemakers. This change would guide coders to use code 37.74 for the insertion of epicardial leads for both defibrillators and pacemakers. This change was adopted for the ICD-9-CM and will become effective on October 1, 2006.

Subsequently a commenter noted to CMS that this coding advice would restrict some defibrillator cases from being assigned to the defibrillator DRGs. The commenter recommended that the following combinations be added to DRGs 515, 535, and 536 so that all types of defibrillator device and lead combinations would be included: code 37.74 and code 00.54; code 37.74 and code 37.96; and code 37.74 and code 37.98. **Premier agrees with the CMS proposal to make this change.**

3. Application of Major Cardiovascular Diagnoses (MCVs) List to Defibrillator DRGs

In the FY 2006 IPPS final rule, CMS published a list of "major cardiovascular conditions (MCVs)". A patient with a condition on this list was expected to have a more complicated patient stay requiring greater resource use. An MCV can be present as either a principal or secondary diagnosis. In the same rule, CMS also adopted new DRGs 547 through 558 as an interim step to better recognize severity in the DRG system for FY 2006 until a more comprehensive analysis of the APR DRG system could be completed.

A commenter has questioned why CMS did not apply the MCV list to the defibrillator DRGs (515, 535, and 536) in addition to the pacemaker DRGs. CMS, however, did not propose additional refinements of the DRGs based on MCVs for FY 2007 in part because of their efforts to propose a broader refinement of the DRG system that would

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focus on consolidated severity-adjusted DRGs. **Premier recommends that CMS reconsider recognizing MCVs in defining the defibrillator DRGs.**

4. Hip and Knee Replacements

In the FY 2006 final rule, CMS deleted DRG 209 (Major Joint and Limb Reattachment Procedures of Lower Extremity) and created new DRGs 544 (Major Joint Replacement or Reattachment of Lower Extremity) and 545 (Revision of Hip or Knee Replacement) because they found revisions of joint replacements to be significantly more resource intensive than original hip and knee replacements. After publication of the final rule, a number of hospitals and coding personnel advised CMS that the DRG logic for DRG 471 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) also includes codes that describe procedures that are not bilateral or that do not involve multiple major joints. The commenters recommended removing codes from DRG 471 that do not specifically identify bilateral or multiple joint procedures. **Premier agrees with the CMS proposal to make this change for FY 2007.**

5. Spinal Fusion

In the FY 2006 IPPS final rule, CMS created new DRG 546 (Spinal Fusions Except Cervical with Curvature of the Spine or Malignancy). After publication of the final rule, CMS received numerous suggestions including:

- Incorporate Bone Morphogenic Protein (BMP), code 84.52 into DRG 546.
- Apply a clinical severity concept to all back and spine surgical DRGS.
- Subdivide the spine DRGs based on the use of specific spinal devices such as artificial discs.
- Create 10 new spine DRGs.

Premier disagrees with the CMS position that it is premature to make changes at this time and we urge CMS to make the suggested changes in the final rule for FY 2007.

EXTERNAL DATA

Premier continues to be concerned about CMS' refusal to make use of external data, especially since these data sometimes are more complete and reliable than program data. We urge CMS to make greater use of external data as well as to facilitate public access to MEDPAR data. Although we very much appreciate timely release of the MedPAR file this year coincident with public availability of the proposed rule, Premier is very concerned that CMS does not make these data available quarterly as it has done

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previously. We made similar comments last year and are hopeful that this year CMS will have a favorable response.

QUALITY

Date for Beginning Collection of Expanded Measures

CMS should delay implementation of the expanded set of measures until July 1, 2006 discharges. The rule, as proposed, is problematic in that it would require hospitals to retroactively collect data on the expanded quality measures for patients who were discharged prior to the rule's implementation—as far back as January of this year. A delay would allow hospitals to allocate resources for this expanded data collection. Not all hospitals participating in Hospital Quality Alliance currently submit the Surgical Infection Prevention measures. A delay until July 1, 2006 discharges would allow hospitals to begin with the Surgical Care Improvement Project revised specifications.

Proposed Measure Expansion

The Institute of Medicine (IOM) report and the proposed rule discuss three measures from The Leapfrog Group (computerized provider order entry, intensive care intensivists, and evidence-based hospital referrals). On behalf of our hospitals, we support consideration of structural measures that meet quality measure standards such as evidence-based, clear operational definitions, delineated process for validation and auditing that ensures reliability (both within and across hospitals) and measure an area of quality within the control of the provider. **We do not believe the three Leapfrog Group measures discussed in the IOM report meet the quality measure standards necessary for inclusion in CMS national quality measurement initiatives.**

Validation

The parameters of the validation process should be stated explicitly and documented. This includes clear definitions, all applicable skip logic, all edits or audits to be applied, and other related information. Hospitals must know exactly *what* is being validated so they may adhere to the specifications during the data collection process. Under the current process, by the time hospitals receive feedback on one quarter's validation, they have already moved onto the next quarter's data collection and can not make changes quickly enough to impact the next quarter. If the validation specs and requirements were clear and well- documented, hospitals could be proactive. Any changes must be communicated clearly and within a timeframe sufficient for hospitals to react and changes their attendant processes. **Premier proposes that any modifications to the technical processes be published 120 days prior to the effective/implementation date.**

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Further, Premier believes that hospitals should be notified of any validation rule changes at least 120 days prior to the hospital data abstraction period.

An alternative method of data validation would be to use the monthly data points of each clinical measure and not rely on chart abstract. A proposed method of validation is to use a process similar to the quarterly Outlier validation Joint Commission requires of the core measure vendors. A monthly data point that exceeds three (3) standard deviations is considered an outlier. When an outlier is identified the hospital is requested to verify the data is accurate. This validation process relies on inter-hospital variability

Joint Commission Initiated Outlier Analysis After Data Transmission

A negative outlier is defined by the Joint Commission as a quarterly data point that is greater than three standard deviations from the national average in a direction that indicates substandard performance. The national average and the standard deviation for the national hospital quality measures are calculated for the quarter using only those data points in the period that have a sample size greater than or equal to 30. The performance measure means and standard deviations will be made available quarterly to measurement systems and hospitals on the Joint Commission's extranet to use for quality improvement activities.

The type of standard deviation described above is based on what is known as inter-hospital variability. The inter-hospital variability is most useful for identifying data points that are "outliers" relative to a population of hospitals.

Since standard deviations and upper limits change from quarter to quarter based on the processing of retransmitted historical data for the hospital or other hospitals using the same measure, a past quarter may become an outlier that was not considered an outlier in a previous quarter's calculations.

Each quarter, after data transmission, the Joint Commission will identify any extreme outlier values that are of significant concern. Before we follow up with individual hospitals, it is critical that the accuracy of these extreme values is verified with the measurement systems. For this reason, measurement systems will review the identified outlier data points and identify one of three possible outcomes. They will confirm either that the values accurately represent the performance of each hospital, indicate that the values may be a result of the measurement systems computation issues, or verify that the values may be a result of hospital data quality issues, all of which will need to be addressed.

This process is efficient and can be completed in one month.

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PLAN FOR HOSPITAL VALUE-BASED PURCHASING PROGRAM

Section 5001(b) of Public Law 109-171 (Deficit Reduction Act of 2005) requires the Secretary of Health and Human Services to develop a plan to implement a value based purchasing program for payments under the Medicare program for subsection (d) hospitals beginning with fiscal year 2009. Such a plan shall include consideration of the following issues:

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(A) The on-going development, selection, and modification process for measures of quality and efficiency in hospital inpatient settings; (B) the reporting, collection, and validation of quality data; (C) the structure of value based payment adjustments, including the determination of thresholds or improvements in quality that would substantiate a payment adjustment, the size of such payments, and the sources of funding for the value based payments and; (D) The disclosure of information on hospital performance.

In developing such a plan, the DRA states the Secretary shall consider experience with such demonstrations that are relevant to the value based purchasing program. Premier is please to be collaborating with CMS on the Premier Hospital Quality Incentive Demonstration and looks forward to evaluating and reviewing the issues with CMS.

HEALTH INFORMATION TECHNOLOGY

While the need for automating the measurement process into electronic medical records (EMR) is a desired goal, the Premier HQI demonstration project is being implemented without the use of EMR. **It is more important to fix ineffective processes than to implement technology that supports retention of broken process systems.** Any lack of automation across the sector is no excuse for delaying quality process improvement. Finally, **any federal funding for physician or hospital information technology should come from "new money/funds" and not be mandated through the hospital conditions of participation.**

HOSPITAL-ACQUIRED INFECTIONS

Premier welcomes the increasing attention to the prevention of hospital-acquired infections (HAI), particularly the transparency of efforts involving both healthcare providers and consumers—we welcome evidence-based approaches to the prevention of adverse events in any healthcare setting. We believe that every effort should be made to eliminate HAIs by applying state-of the-art science even as our hospitals care for sicker patients in an increasingly complex environment. We also recognize this is only accomplished in a culture of safety that promotes fixing systems over assigning blame.

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While zero tolerance of HAIs is a goal all our members endorse, it is important to be aware that systematic review of several studies demonstrates that the preventable proportion of HAIs ranges between 10 to 70 percent; for surgical site infections in particular, this range of preventable infections is between 40 to 60 percent.[1] We note the CMS Surgical Care Improvement Project (SCIP) goal in this regard is a target of 25 percent reduction in morbidity and mortality associated with surgical care.

After studying CMS' proposal, Premier agrees with the intent of the proposed change. We do not think that HAIs which could be prevented based on interventions developed from scientifically sound, evidence-based practices should receive higher payments.

As Premier participates in a variety of infection prevention strategies, we are pleased as well to acknowledge dramatic successes in infection reduction achieved by implementing an entire group (i.e., bundle) of evidenced-based practices. This strategy results in better outcomes than when each practice is implemented individually. There are numerous well publicized initiatives that demonstrate improved outcomes when all the right processes occur together. In areas specifically measuring HAI incidence, unprecedented reductions in rates of central line-associated bloodstream infections (CLA-BSI) and ventilator-associated pneumonia (VAP) for example, have been reported by hospitals participating in local, regional, state and national initiatives such as the Pittsburgh Regional Health Initiative, Maryland Patient Safety Center, Michigan's Keystone Center and others. However, even within these successful collaborations, HAIs occur despite near complete adherence with high quality, validated processes of care in the participating facilities. These findings suggest that additional studies are needed to elucidate other modifiable risk factors for HAIs. Such limitations of science-based interventions have implications for providers even with payer incentives for prevention.

Premier would like to focus on one of the most notable initiatives related to surgical site infection (SSI) –namely CMS's success using bundling in the Surgical Infection Prevention Project SIPP-- now developed into CMS's SCIP. SCIP has built its processes for preventing SSI from a series of widely accepted evidence-based (EB) guidelines including (1) the *CDC Guidelines for the Prevention of Surgical Site Infection* in which the literature is reviewed and categorized based on the weight of evidence in the recommendations[2]; (2) peer-reviewed guidelines on surgical antibiotic prophylaxis[3]; and

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[1] Harbarth S,Saxa H, Gastmeier P. The preventable proportion of nosocomial infections: an overview of published reports. Journal of Hospital Infection (2003) 54, 258–266

[2] CDC. The "Guideline for Prevention of Surgical Site Infection, 1999" is available online at www.cdc.gov/ncidod/dhqp Published simultaneously in Infection Control and Hospital Epidemiology; AJIC: American Journal of Infection Control 1999;27:97-134

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(3) guidelines for antibiotic prophylaxis in cardiac surgery[4]. SCIP has already demonstrated that in *certain* patients, in *certain* procedures, SSIs *can* be prevented, and rates certainly reduced when such guidelines are applied. For example, in the initial SIP collaborative, a one-year demonstration project sponsored by CMS concluded that "the infection rate decreased 27 percent, from 2.3 percent to 1.7 percent in the first versus last three months."[5]

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Limitations

What we do *not* know from applying even the best of EB guidelines in prospective controlled trials is –*how many can truly be prevented* as such initiatives continue over time throughout all of our hospitals. Therefore, cases which could *reasonably have been prevented are only those in whom all evidence based practices have been followed and indeed no infection develops.*

We *do* know that thousands of our hospitals are demonstrating their determination to reduce infections by applying these guidelines systematically through participation in SCIP. In the selection of two conditions involving just surgical procedures, conditions already demonstrating good results when bundles are applied properly, the challenge will remain to avoid penalizing hospitals for a specific DRG grouping which cannot separate an identified HAI from associated co-morbidities associated with patients' underlying conditions such as diabetes.

Using the example of SCIP, if a hospital-associated SSI was identified in a patient, the direct method to identify whether it was truly preventable would involve a review process to determine if the case met *all* the EB SCIP surgical measures currently applicable to that specific patient. If this SSI case analysis shows that the hospital did not implement and document all SCIP measures, the hospital would not receive the reimbursement rate for the associated CC.[6] However, if the hospital documented that all possible processes were

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[3] Bratzler et al. Antimicrobial Prophylaxis for Surgery: An Advisory Statement from the National Surgical Infection Prevention Project. CID 2004:38 (15 June) 1706.

[4] Antibiotic Prophylaxis in Cardiac Surgery - Duration of prophylaxis. *Report from the Society of Thoracic Surgeons Workforce on Evidence Based Surgery.* ©2005 The Society of Thoracic Surgeons. approved exception for discontinuance of antibiotic prophylaxis. Available from http://www.sts.org/sections/aboutthesociety/practiceguidelines/antibioticguideline/

[5] Dellinger EP, Hausmann SM, Bratzler DW, et al Hospitals collaborate to decrease surgical site infections. Am J Surg. 2005 Jul;190(1):16-7.

[6] Nolan T,Berwick.D. All-or-None Measurement Raises the Bar on Performance JAMA, March 8, 2006—Vol 295,1178-1171

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applied, the hospital should not carry the financial burden for the patient's SSI, since the hospital has complied with the 'state of the art' in terms of infection prevention. This approach would provide incentives to hospitals to apply all recommended practices, and would fairly reimburse cases for which a HAI develops *despite* adherence to such practices.

Such a process would permit learning more about what those "unknown factors" are that lead to infection even when there is adherence to all known EB practices. Hospitals could continue to use tools like root cause analysis to determine why some patients still develop infection despite applying all current scientific practices known to prevent infections. This approach would be viewed positively by patients, would encourage hospital staff to work even harder to improve, and most importantly would teach us even more than we currently know about infection prevention. This approach would also support accountability to the patient –the most important factor in this equation - while still promoting a learning environment in the hospital with regard to infection prevention.

However, this approach is impractical for numerous reasons; including the data analysis burden to CMS, as well as a hospital appeals process which would have to be defined and developed in order to fairly exclude individual cases from payment.

CMS will be challenged to determine the truly preventable infections and would not, and should not, penalize hospitals for what they cannot prevent or control. We would therefore suggest developing other approaches that do not rely on patient level data, but function as a proxy for patient-level review.

Recommended Approach

Premier proposes a measurement system that emphasizes adherence with systems and processes of care that have achieved a high quality of evidence demonstrating correlations with reduction in infection rates. Documentation of systems or processes is typically straightforward and subsequent analyses can be employed to determine correlation. These systems and the frequency of outcomes, such as SSIs, should use aggregate data to establish thresholds for when the DRG CC change is actually applied.

We recommend as one possible approach that hospitals should:

- Accept that patients with the selected condition may be identified as having a specific HAI (that may or may not be preventable).
- Accept that such identified cases will result in maintaining the lower-payment DRG *unless* they can provide measurable achievements that demonstrate the application of EB practices in a variety of initiatives. These can include any

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number of practices in the local, regional, state or federal levels. Thresholds could be developed not just for participation and reporting but actual levels of performance—even as CMS moves forward in its stated direction of "pay for performance." Once again we refer to initiatives like PRHI, Keystone, and SCIP to learn what thresholds would be reasonable based on each community's success and local patient populations.

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This may not be the optimum moment to suggest the initial conditions that most closely correlate with preventable HAIs given CMS's proposal to move to a consolidated DRG system, the complexities of coding and the need for expertise on coding and the DRG GROUPER. Premier is prepared to provide input as these processes develop and are implemented. CMS is aware of the multiple EB guidelines from CDC, and without listing them all at the moment, we offer a few other recent resources beyond the prevention of surgical site infections noted earlier.[7] [8]

What Premier has learned and can share is that the need to continually improve our members' safety culture, working closer as teams and applying the evidence gained in studies are all key strategies to improve safety and quality of care. The processes are critical, intensive, and complex but rewarding in the achievement of greatly reduced incidence of infection.

We urge CMS to consider in this federal mandate continuation of CMS' current direction that *rewards good performance*, supports hospital efforts to develop and maintain a non-punitive culture of safety, and yet provides the necessary accountability implied in the current Congressional budget language. Premier would ask that CMS link the proposed language to its current successful implementation of *process measurement* –even as the outcome of such processes is being validated in various methods.

We are eager to participate with CMS in the development of the final rule and more specifically with the development of indicators and systems to implement the rule once finalized. We are committed to improving the safety of healthcare and look forward to working with CMS toward this goal.

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[7] McKibben L, Horan, T, Tokars JI, Fowler G, Cardo DM, Pearson ML, Brennan PJ. and the Healthcare Infection Control Practices Advisory Committee* Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. Am J Infect Control 2005;33:217-26.

[8] McKibben L, Fowler G, Horan T, Brennan PJ. Ensuring rational public reporting systems for health care–associated infections: Systematic literature review and evaluation recommendations Am J Infect Control 2006;34:142-9.

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In closing, Premier appreciates the opportunity to comment on the FY '07 IPPS proposed rule. Please do not hesitate to contact me, Margaret Reagan, corporate vice president of Premier at 202-879-8003 if you would like to discuss these comments further.

Sincerely,

Margaret Reagan

Margaret Regan
Corporate Vice President

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158

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June 12, 2006

Hon. Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: 42 CFR Parts 409, 410, 412, 413, 424, 485, and 489
Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan,

This letter presents comments and recommendations of the Acute Long Term Hospital Association (ALTHA) to certain aspects of the proposed annual payment rate updates, policy changes, and clarifications under the prospective payment system for inpatient hospitals (IPPS) for fiscal year (FY) 2007, which were published by the Centers for Medicare & Medicaid Services ("CMS") on April 12, 2006.

ALTHA represents over three hundred long-term acute care hospitals (LTACHs) across the United States. ALTHA member hospitals provide highly specialized care for critically ill patients with multiple, medically complex problems. We are pleased to submit these comments on the proposed regulation.

I. DRGs: Severity of Illness

General Description

For 2008 (or sooner) CMS is proposing to shift from the diagnosis related group (DRG) patient classification system it currently uses for short-term acute care hospitals to a system based on the all payer refined diagnosis related group (APR-DRG) classification system. The focus of the current IPPS DRGs is on complexity, defined as the relative volume and types of diagnostic, therapeutic, and bed services required for the treatment of a particular illness, while the focus of the APR-DRG system is on patient severity of illness.

Severity is measured in the APR-DRG system using physiologic decompensation or organ system loss of function. CMS states, "The underlying clinical principle of APR-DRGs is that the severity of illness of a patient is highly dependent on the patient's underlying problem and that patients with high severity of illness are usually characterized by multiple serious diseases or illnesses." Another difference in the two

systems has to do with how they subclassify patients within a given diagnostic category. The DRG system further classifies patients based on the presence or absence of a complication or comorbidity (CC). In the APR-DRG system further classification is made according to whether patient complications and comorbidities are minor, moderate, major or extreme. This process is referred to as the severity of illness determination.

Determining the patient's severity of illness in the APR-DRG system is an iterative, three phase process that considers multiple factors such as the combination of a patient's principal diagnosis, age, and secondary diagnoses. The classification begins by assigning each secondary diagnosis a severity level (minor, moderate, major or extreme) and then modifying the level based on the patient's APR-DRG and other characteristics. For example, chronic renal failure is assigned a level of moderate, but is increased to major because the patient's APR-DRG is diabetes. Once all of the secondary diagnoses have been assigned a level with modifications for other factors, the levels are combined into one severity of illness subclass (also minor, moderate, major or extreme) based on the level of the most severe secondary diagnosis. In the final phase, the subclass designation is modified based on specific combinations of factors such as the principal diagnosis, age and categories of secondary diagnoses.

CMS considered, but did not propose, to use a modified version of the APR-DRGs for LTACHs in the original rule implementing the prospective payment system (LTACH PPS) for LTACHs in 2002. In previous IPPS rules, CMS has discussed adopting APR-DRGs as the basis of an alternative patient classification system to DRGs. In this rule, CMS proposes a "consolidated severity-adjusted DRG system" based on the APR-DRGs, but with significant modifications.

These modifications include reducing the overall number of APR-DRGs by collapsing low volume APR-DRGs, potentially adding a complexity adjustment, and recalculating the Federal base payment rate and outlier threshold. The change from DRGs to an APR-DRG based system, the proposed modifications to the APR-DRG system into what CMS calls its consolidated severity-adjusted system, and the schedule for implementation proposed by CMS, raise issues on which ALTHA would like to comment.

Analysis of Proposal

We are supportive of CMS' efforts to develop a patient classification system that accounts for comorbidities and severity of illness. Because LTACHs specialize in the treatment of medically complex patients requiring long hospital stays, ALTHA supports CMS efforts to improve the accuracy of the Medicare IPPS through inclusion of aspects of patient care that recognize the full range of treatments provided to patients and that are adjusted for patient acuity.

Since the APR-DRG system was proposed for the LTACH PPS in 2002, ALTHA has used this system to conduct many analyses of LTACH patients. Most recently, ALTHA used the 3M™ APR-DRG grouper to analyze the severity of illness of full-stay and short-stay patients to demonstrate the high severity of illness that is prevalent across all LTACH patients, for the purposes of responding to the CMS proposed change in

payment policy for so-called "short-stay outlier" cases in the LTACH PPS. However, we have not recently used to the APR-DRG grouper to determine how overall payments to LTACHs would change if payment under the LTACH PPS were based on APR-DRGs, and in order to fully respond to this proposed rule, we and the short-term acute care hospitals would have to conduct those analyses.
Second, ALTHA is concerned that we, and more importantly the affected short-term acute care hospitals, will not be able to fully analyze the consolidated severity-adjusted system that CMS is proposing by June 12, 2006 – the day that comments on the proposal are due. Unfortunately, the APR-DRG grouper as it currently exists does not exactly match the new system CMS is proposing, because CMS has proposed what we believe to be significant modifications of the standard APR-DRG system. The most significant modification includes the collapsing of the over 1,200 APR-DRGs into 860 categories under the consolidated CMS proposed system.

In addition to the newness of concept of using the APR-DRG system for payment and the lack of time to meaningfully analyze the consolidated APR-DRG system, ALTHA finds that there are many aspects of the proposed system that are not well-defined, such as how an adjustment for complexity might be calculated. For certain subpopulations of Medicare patients in both short-term acute care hospitals and LTACHs, expensive medical technologies are employed, and we believe that the Medicare payment system should reflect the hospital's costs of treating these subpopulations. Again, we believe that we, and many short-term acute care hospitals, cannot properly propose solutions for accounting for patient complexity in the short time period allowed for public comments.

While in this regulation CMS explicitly states that the consolidated severity-adjusted system would not apply to LTACHs in 2008 (or sooner), ALTHA notes that no description of what a consolidated LTC APR-DRG system would look like is offered. As CMS considers applying the new IPPS system to LTACHs, in particular one aspect of the consolidated system may not be transferable to LTACHs. For the low-volume IPPS APR-DRGs, CMS has consolidated by major disease category (MDC) many of the subcategories found in the standard APR-DRG system. Under the current LTC-DRG system, the low-volume LTC-DRGs also are collapsed, but it is unclear at this time how a similar modification of the DRGs under an LTC APR-DRG system would interact with the SOI level reductions in the consolidated system CMS is proposing. ALTHA notes for example that when the 3M™ APR-DRG grouper is used to put LTACH patients into severity of illness categories, approximately 69% of LTACH patients are in SOI levels 3 and 4. Table D in the proposed rule shows that approximately 32% of short-term general hospital patients would be so categorized; this indicates that while CMS may find it appropriate to collapse some of the APR-DRGs due to low-volume into SOI category 4 for the IPPS, this may not be an appropriate step in developing a modified APR-DRG system for LTACHs.

Recommendation

While we support in concept CMS's proposal to improve the accuracy of the IPPS payment system to account for patient severity, we cannot yet support the proposed consolidated severity-adjusted system because we have been provided with insufficient

detail and time to fully analyze the potential impacts of the new system on LTACHs. In particular, ALTHA is concerned that unless a modified grouper software is made available during the public comment period, affected hospitals cannot fully respond to this proposed rule. However, as CMS refines this system and allows for meaningful comments from the industry, we look forward to engaging with CMS in this process. We reiterate that if the LTC-DRGs were to be replaced by this consolidated system, additional considerations for LTACH patients should be taken into account.

II. LTC-DRGs

General Description

On an annual basis, CMS updates the long-term care diagnostic-related groups (LTC-DRGs) and their associated relative weights. The LTC-DRG weights are calculated to reflect the resources used by an average Medicare inpatient LTACH case for each LTC-DRG. The relative weights are updated each year to account for changes in the reported costs per LTC-DRG relative to all other LTC-DRGs. CMS used the December 2005 MedPAR update file to calculate the proposed weights for FY2007.

Analysis of Proposal

In the LTC-DRG reweighting process, CMS does not conduct the reweighting in a budget-neutral manner, unlike the process used for the IPPS. The result of this non-budget-neutral process in the proposed rule is that CMS is proposing new LTC-DRG weights that would reduce total Medicare payments to LTACHs by an estimated 1.4% in FY2007. Table 1 below shows the proposed weights for several of the most frequently assigned LTC-DRGs.

ALTHA notes with concern that, if the proposed rule is adopted, FY 2007 will be the second year in a row that major reductions will be made in the weights for LTC-DRGs 87, 89 and 271. ALTHA is concerned because annual fluctuations in payments, downward or upward, can be destabilizing for Medicare providers, particularly as they transition to a new payment system. Significant year-to-year changes in payments, whether the result of weight adjustments or other payment policy changes, can make it difficult for Medicare providers to plan for the future. In this uncertain environment, it can be challenging for providers to effectively operate their facilities and maintain the highest quality of care for their Medicare patients.

Table 1: Common LTACH LTC-DRGs and Proposed FY2007 Weights

LTC-DRG	Description	FY 2006 Relative Weight	Proposed FY 2007 Relative Weight	Percent Change
87	Pulmonary Edema & Respiratory Failure	1.0816	1.0305	-4.7%
88	COPD	0.6585	0.6417	-2.6%
89	Simple Pneumonia & Pleurisy Age > 17 with CC	0.6987	0.6826	-2.3%
271	Skin Ulcers	0.8720	0.8290	-4.9%
462	Rehabilitation	0.5787	0.5847	1.0%
475	Respiratory Diagnosis with Ventilator Support	2.0831	1.9875	-4.6%

ALTHA notes that the non-budget-neutral manner with which CMS annually updates the LTC-DRG weights creates a peculiar incentive for LTACHs seeking to maximize the efficiency and quality of care provided to their Medicare patients. When LTACHs provide relatively more efficient care from one year to the next, the costs reported for providing that care will be lower than the weight for the LTC-DRG to which the patients are assigned. Under current CMS policy, the LTC-DRG weight in subsequent years is lowered to better match the (more efficient) reported costs for those cases. Non-budget-neutral reweighting has the effect of reducing for each LTC-DRG the difference between cost and reimbursement to zero. While this outcome may appear to be consistent with the goal of a prospective payment system (which can be described as paying LTACHs, on average, for the cost of treating their case), it penalizes providers seeking to improve the efficiency of their care by taking away their economic incentive for improving efficiency, i.e., a positive revenue margin. Reweighting the LTC-DRGs in a budget-neutral manner, as is done in the inpatient PPS, maintains the same overall level of reimbursement available to hospitals and thus provides hospitals with the incentive to provide more efficient care on a DRG-by-DRG basis.

In addition, CMS recently finalized a zero market basket update for LTACHs. The stated rationale for this policy was that there has not been an "actual" increase in casemix for LTACH patients, but instead CMS asserts that there has been an "apparent" increase in casemix due to improved coding practices. Accordingly, CMS claims that LTACHs have not experienced cost increases that would justify paying LTACHs a market basket to account for the increase in the cost of inputs experienced by health care providers. ALTHA is very concerned that this rationale for finalizing the policy for zero market basket for LTACHs is the exact same rationale that the non-budget neutral DRG re-weighting is designed to address. Specifically, individual DRG weights go down under

CMS' methodology if costs in that particular DRG do not increase commensurate with the payment weight. If, as CMS asserts, actual casemix does not increase, then DRG weights will be adjusted accordingly. As a result, CMS has made two payment adjustments for LTACHs in the same rate year for the same purpose. This type of payment penalty is unprecedented and unwarranted.

Finally, CMS has failed to evaluate the impact of the DRG re-weighting proposal on the overall adequacy of LTACH payment rates.

Recommendation

ALTHA recommends that prior to implementing the LTC-DRG reweighting in a non-budget-neutral manner, CMS should conduct an analysis of the impact of the proposed reweighting on LTACH payment adequacy. In the past 12 months, CMS has lowered payment rates to LTACHs twice (a 4.2% reduction payments due to the LTC-DRG reweighting process for FY2006 and a 3.7% reduction due to the change in payment methodology for short-stay outlier cases beginning in RY2007) and has chosen not to provide a LTC PPS market basket update for RY 2007, even while acknowledging that LTACHs' costs of providing care will increase by an estimated 3.4% in the same year.

ALTHA has conducted preliminary analyses which suggest that the combined impacts of these recent CMS payment changes will be significantly reduced LTACH margins. Since we believe that overall Medicare payment adequacy is necessary to ensuring Medicare beneficiaries access to high-quality care, we respectfully recommend that CMS delay implementing any further LTC-DRG reweighting, especially if conducted in a non-budget-neutral manner, until the agency has assessed the combined effects of the proposed reweighting with other recent payment policy changes on the overall adequacy of Medicare payments to LTACHs.

III. Changes in the Methodology for Determining LTACH Cost-to-Charge Ratios (CCRs) and LTACH PPS Outlier Payment Reconciliation

General Description

In this rule CMS provides an impact analysis of changes to the methodology for determining LTACH cost-to-charge ratios (CCRs) and reconciliation of high-cost and short-stay outlier payments. CMS proposes a total CCR ceiling of 1.313 under the LTC PPS effective October 1, 2006.

Analysis

CMS notes based on the most recent complete IPPS and LTACH CCR data, no LTACHs currently have a CCR greater than the proposed 1.313 ceiling, and therefore the proposed policy change will not significantly impact LTACH payments.

Recommendation

We thank CMS for providing an analysis of the impact of this proposed change in the methodology for calculating the CCR limits. ALTHA supports this proposal.

Sincerely yours,

William Walters
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159

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June 12, 2006

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Attention: CMS-1488-P

RE: DRGs: Severe Sepsis

Dear Administrator McClellan:

The Society of Critical Care Medicine (the "Society") appreciates this opportunity to comment on the proposed rule for changes to the hospital inpatient prospective payment systems and fiscal year 2007 rates. Specifically, the Society wishes to comment on MDC 18 (Infectious and Parasitic Diseases) and the need for separate DRGs, medical and surgical, for severe sepsis.

The Society is the leading professional organization dedicated to ensuring excellence and consistency in the practice of critical care medicine. With more than 13,000 members worldwide, the Society is the only professional organization devoted exclusively to the advancement of multiprofessional intensive care through excellence in patient care, professional education, public education, research and advocacy. Members of the Society include intensivists, critical care nurses, critical care pharmacists, clinical pharmacologists, respiratory care practitioners and other professionals with an interest in critical care, including physician assistants, social workers and dietitians.

As CMS noted in the proposed rule, the Society has met with CMS officials and provided data on the need for two new DRGs for severe sepsis patients with organ support -- a medical DRG and a surgical DRG. As described in more detail below, the MedPAR data clearly show that patients with severe sepsis with organ support are a clinically coherent population with very similar resource use. These patients are not simply the most costly cases in a DRG. Rather, they are cases with a common acute illness, managed in a similar clinical fashion, with similar resource use and clinical outcomes.

Based on the 2005 MedPAR data, the mortality rate of Medicare patients with severe sepsis with organ support was 43%. One in five of all the Medicare hospital mortalities are patients with severe sepsis.

We do believe that the severity-adjusted DRGs proposed by CMS are a step in the right direction, and we commend CMS for proposing to link Medicare payments more closely to the

severity of illness. These are the patients that Society members treat and we look forward to working with CMS to further refine this methodology so that it appropriately recognizes the costs that hospitals expend to treat these patients.

However, the new system as currently proposed, and as CMS acknowledges, does not accurately reflect the complexity of care that is often independent of severity of illness. That is, the APR DRGs proposed by CMS in this new system do not include the improvements that CMS itself has made in the categories of DRGs in recent years.

Thus, this new system as proposed would not fully address the needs of the severe sepsis cases, particularly with respect to surgical patients, as further described below. We believe that the severity-adjusted methodology, when further refined to take into account complexity of care, will lead eventually to a more appropriate reimbursement for severe sepsis. Nevertheless, there should be no further delay in creating new DRGs for severe sepsis as we wait for this needed refinement to the newly proposed system.

In sum, we strongly believe that severe sepsis patients must be segregated into their own DRGs for fiscal year 2007. This matter should be a CMS priority. Based on a review of the 2005 MedPAR database, the costs of caring for these patients is greater than the DRG payment for these patients in the overwhelming majority of cases. Indeed, for the minority of cases where the Medicare payment actually covers the cost of care, two-thirds of those patients die in the hospital.

Our comments will respond to each concern raised by CMS in the proposed rule concerning the creation of new DRGs for severe sepsis.

CMS Comment: "The commenter [SCCM] requested that all cases in which severe sepsis is present on admission, as well as those cases in which it develops after admission (which are currently classified elsewhere), be included in this new DRG."

CMS claimed that the Society requested that all severe sepsis cases be placed in a single DRG for both principal and secondary diagnosis of severe sepsis.

Response: The Society presented different possible scenarios, each of which included both a medical and a surgical DRG, recognizing the vastly different resource use that is associated with surgical cases. One alternative the Society presented was for a pair of Pre-MDC DRGs to capture all cases of severe sepsis requiring organ support. These cases are among the most expensive in the whole inpatient prospective payment system, and the new DRGs would be similar in structure to the current tracheotomy with prolonged mechanical ventilation DRGs that do not make any specific requirement concerning the exact principal diagnosis for the case. The primary difference would be that instead of looking only at mechanical ventilation, other organ support technologies such as use of renal replacement therapy and vasopressors to manage septic shock would be included as well as a diagnosis of severe sepsis or septic shock.

The Society believes that grouping this clinically coherent, resource intensive group of patients into these **two** DRGs would best capture this group of patients who are uniform in their disease management but coming from body system infection or surgical sites in the administrative system in a way that parallels their clinical situation.

A second scenario the Society presented was simply to divide each of DRGs 415 and 416 into DRGs with and without severe sepsis cases. There is a large enough number of cases of severe sepsis in these DRGs with very different resource use and outcome from the non-severe sepsis cases that splitting these two DRGs into severe sepsis and non-severe sepsis DRGs would indeed be warranted as detailed further below.

CMS Comment: "We did not believe the current clinical definition of severe sepsis was specific enough to identify a meaningful cohort of patients in terms of clinical coherence and resource utilization to warrant a separate DRG. Sepsis is found across hundreds of medical and surgical DRGs, and the term 'organ dysfunction' implicates numerous currently existing diagnosis codes."

Response: The current definition of severe sepsis was adopted following a 1992 consensus panel of the American College of Chest Physicians and the Society of Critical Care Medicine, and reaffirmed ten years later in a 2002 consensus conference. The panel defined severe sepsis as a systemic inflammatory response to infection that leads to acute organ dysfunction.

The definition has been adopted by the 11 different professional organizations that sponsored the panel and has been successfully used to identify tens of thousands of patients enrolled in clinical trials seeking ways to reduce mortality and morbidity associated with severe sepsis. Further, this definition has been used in more than 30 large-scale clinical trials.

The Society of Critical Care Medicine is surprised by CMS's unsupported contention that severe sepsis does not define a clinically coherent patient population. Thousands of our member professionals daily identify and care for these patients, the majority of whom are Medicare beneficiaries. Quality improvement initiatives for the care of severe sepsis patients have been developed by the Voluntary Hospital Association and the Surviving Sepsis Campaign. These quality measures identify patients using the same criteria. Health care practitioners work each day to improve the care of severe sepsis patients using these criteria to identify these patients.

The same disease state can be found across many DRGs for two basic reasons. First, the disease state can be very common, and second, it could be that there is no particular place for those cases to go. It is surprising that CMS uses the fact that severe sepsis cases are spread across hundreds of DRGs, as a reason to not provide separate severe sepsis DRGs, when these cases are dispersed widely because the lack of particular DRGs for these cases leaves no alternative.

A comparative example is instructive. Acute myocardial infraction (AMI, ICD-9-CM 410.XX)

was used in 546,696 discharges in the FY 2005 MedPAR database. These cases were spread across 416 different DRGs, because it is a common diagnosis. However, in contrast to severe sepsis case where there are no specific DRGs, 77% of AMI cases were grouped into DRGs specifically associated with coronary artery disease.

With respect to clinical coherence, severe sepsis cases are clinically coherent with a common underlying problem (systemic inflammatory response to infection) leading to a common set of complications (acute organ dysfunctions independent of the site of infection) and managed in a common way (advanced life support in intensive care units to manage the acute organ dysfunctions that would otherwise be fatal).

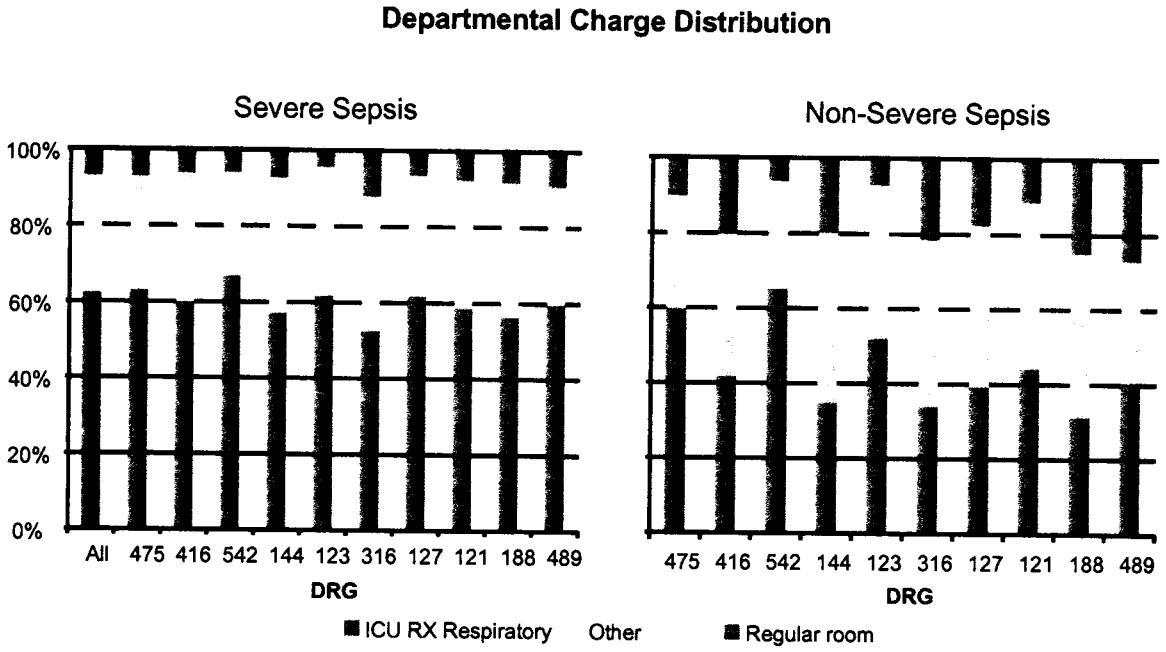
This clinical coherence leads to resource use coherence, making the severe sepsis cases in different DRGs more like each other than the other cases in their current DRGs. We examined the degree to which severe sepsis cases are more like each other than their source DRGs by identifying the 10 medical and 10 surgical DRGs with the most severe sepsis (995.92) and septic shock (785.42) cases that required organ support in the FY 2004 MedPAR database.

Taking all cases in these 20 DRGs, relative resource use was examined in three consolidated cost centers: routine care; ICU, coronary care, pharmacy, and respiratory therapy; and all remaining cost centers. The proportion of total charges in each of the consolidated cost centers was examined for those with and without severe sepsis across the DRGs.

Among the medical DRGs, routine care accounted for 7.4% of charges in the severe sepsis cases with a standard deviation of 2.1% between the DRGs; in contrast, the standard deviation for the difference between the severe sepsis and non-severe sepsis cases across DRGs had a standard deviation three times greater (6.3%). That is, severe sepsis cases were three times more like each other than like the other cases in their current DRGs.

The ICU, pharmacy, respiratory therapy consolidated cost centers behaved in a similar fashion, accounting for 59.7% of charges in the severe sepsis cases with a standard deviation of 4.1% and a standard deviation between severe sepsis and non-severe sepsis cases twice as great (8.1%). Therefore, as shown in Figure 1, medical severe sepsis cases are much more like each other than they are like the other cases in the DRGs from which they are drawn.

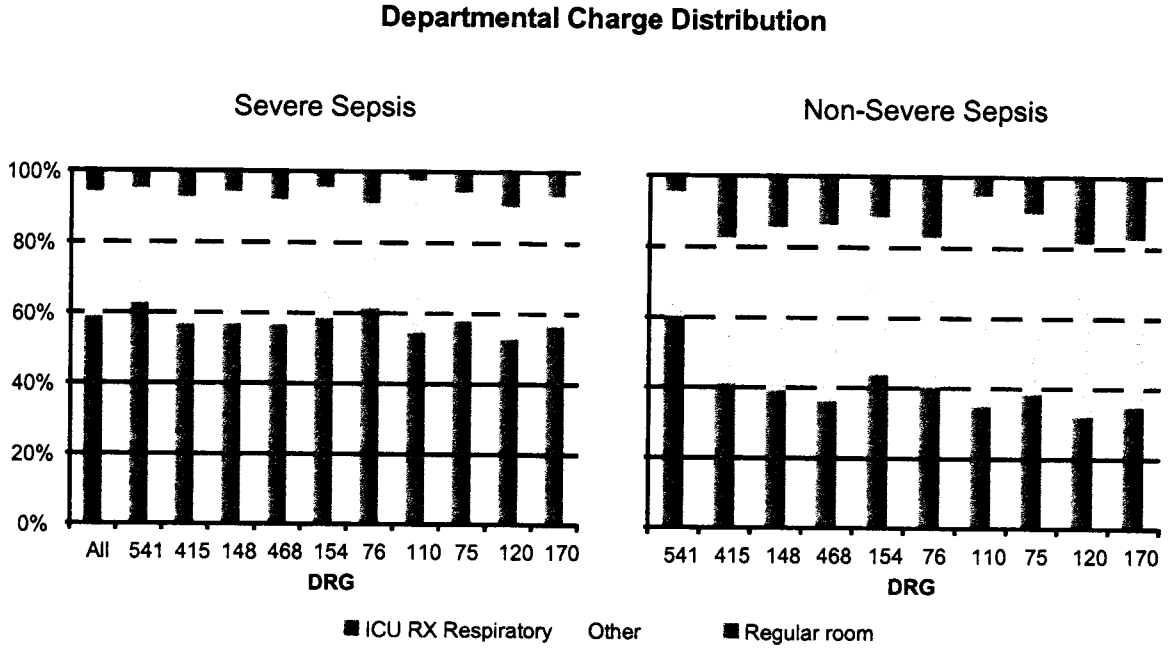
Figure 1 Resource use profile for major medical DRGs with and without severe sepsis



Among surgical DRGs, routine care accounted for 6.2% of charges in the severe sepsis cases with a standard deviation of 2.2% between the DRGs; in contrast, the standard deviation for the difference between the severe sepsis and non-severe sepsis cases across DRGs had a standard deviation 50% greater (3.4%). That is, severe sepsis cases were 50% more like each other than like the other cases in their current DRGs for routine care charges.

The ICU, pharmacy, respiratory therapy, and consolidated cost centers behaved in a similar fashion, accounting for 57.4% of charges in the severe sepsis cases with a standard deviation of 3.0% and a standard deviation between severe sepsis and non-severe sepsis cases twice as great (6.9%). Therefore, surgical severe sepsis cases are much more like each other than they are like the other cases in the DRGs from which they are drawn. (Figure 2)

Figure 2 Resource use profile for major surgical DRGs with and without severe sepsis



Therefore, severe sepsis cases across DRGs, as expected, are much more like each other, *i.e,* clinically coherent, and not like the non-severe sepsis cases in their current DRGs. Severe sepsis cases have both a clinical and resource use coherence that justifies their consolidation into a few DRGs instead of being spread across the whole inpatient prospective payment system.

In trying to understand the clinical and resource coherence of severe sepsis cases, CMS officials wondered whether severe sepsis cases simply represent the tails of the cost distributions from many different DRGs, *i.e.*, the most expensive cases. Any set of discharges (DRG) must have cases that are most expensive. CMS wondered if we were simply attaching the name "severe sepsis" to what were simply the most resource intensive cases in different DRGs.

However, we identified cases based on their disease characteristics, and then we found their cost distribution. Many severe sepsis patients die quickly and have relatively low costs (in two-thirds of all cases where the DRG payment actually covers the costs of treating patients with severe sepsis, the patients die quickly).

However, to respond to the CMS concern that these are just the most expensive cases in existing DRGs, and that removing this tail would just leave another, we investigated the extent to which severe sepsis cases are prevalent in the high cost tails of each DRG. Using the FY 2005 MedPAR discharge database, we found the 90th percentile point of standardized charges for each DRG and selected all cases where the standardized charges for the case exceeded the 90th percentile point for its DRG.

Severe sepsis cases were only 17% of cases in the high cost tail. While this is a much greater concentration than severe sepsis overall, severe sepsis cases are not in any sense simply the most expensive cases in any DRG. Therefore, severe sepsis cases that are identified based on their clinical characteristics are not simply the most expensive cases.

CMS Comment: "While we recognize that Medicare beneficiaries with severe sepsis are quite ill and require extensive hospital resources, in the past we have not found that they can be identified adequately to justify removing them from all of the other DRGs in which they appear."

Response: While there has been some confusion over the use of the 995.9 family of codes over the past three years, this confusion has been mainly associated with the other codes and not the severe sepsis (995.92) code. In particular, 995.91 (formerly systemic inflammatory response syndrome associated with infection without organ dysfunction) caused a degree of confusion since it could be applied to almost any case of hospitalized infection, and it was not clear to coders when and how it should be used.

An examination of the MedPAR database for the three years that severe sepsis codes have been available, 2003-2005, reveals that the adoption of codes for severe sepsis (995.92) and septic shock (785.52) is proceeding aggressively from only 6,676 uses in 2003 to 102,298 in 2004, and 159,170 in 2005. The mortality rate for these patients coded as having severe sepsis or septic shock is 43% based on the MedPAR data. This very high mortality rate, which is similar to that appearing in the clinical research literature, should go far in allaying CMS concerns that the severe sepsis codes would be used in patients with a low severity of illness.

While improved coding guidance is welcome, there are more than enough cases currently being identified to make changes to the DRG classification. Again, looking at the FY 2005 MedPAR database, we found that severe sepsis (995.92) is within the 150 most often coded diagnoses and that septic shock (785.52) is within the top 200 diagnoses after just two years. **Taken together (9995.92 and 785.52), severe sepsis is one of the top 100 diagnoses recorded in the 2005 MedPAR database. Therefore, there is more than enough data available to make changes.**

CMS Comment: "For this FY 2007 proposed rule, we again received a request to consider creating a separate DRG for patients diagnosed with severe sepsis. The information and data available to us from hospital bills with respect to identifying patients with severe sepsis have not changed since last year."

Response: Prior to this past year, communication with CMS was limited to FY 2003 data, where there was little use of the severe sepsis code in its first year, with only 6,676 cases identified. The most recent discussions that the Society of Critical Care Medicine had with CMS made use of FY 2004 data, which showed 102,298 cases of severe sepsis and septic shock. The 2005

MedPAR data shows 159,170 cases of severe sepsis or septic shock. Clearly, there has been a change with respect to identifying patients with severe sepsis. CMS now has at its disposal sufficient data to better understand the current use of the severe sepsis codes, but has simply not used it.

CMS Comment: "We believe that implementation of the modified SIRS diagnosis codes and the updated coding guidelines over the next year could begin the process of improving data for this group of patients. The desired outcome is to be able to better evaluate Medicare beneficiaries with severe sepsis with regard to their clinical coherence, resource utilization, and charges."

Response: The only coding modification that directly effects the severe sepsis coding is to change its name to "Severe Sepsis," and that there is no need to use both severe sepsis (995.92) and septic shock (785.52) in the same discharge. We believe that the 260,000 uses of severe sepsis and septic shock in 2004 and 2005 represent a very large and consistent body of data to use in defining new DRGs for severe sepsis cases.

If CMS finds the creation of the Pre-MDC DRGs too problematic at this point, then a much simpler modification would lead to substantial improve in the DRG system's ability to recognize the burden of severe sepsis. The simplest thing to do would be to split DRGs 415 and 416 into separate parts for those with and without severe sepsis.

Cases with severe sepsis or septic shock account for 24% (N=65,841) of the 276,977 cases in DRG 416 in FY 2005 (Table 1). For this DRG, cases with a severe sepsis diagnosis have triple the mortality (40.3% vs 13.6%), have five times the use of mechanical ventilation (24.4% vs. 13.6%), and have 45% higher standardized charges than cases without a severe sepsis diagnosis.

Splitting DRG 415, cases with a severe sepsis diagnosis have quadruple the mortality (31.3% vs. 7.4%), have five times the use of mechanical ventilation (34.8% vs. 7.1%), and nearly double the standardized charges ($99,314 vs. $56,612) than cases without a severe sepsis code.

A DRG created from the severe sepsis coded portion of DRG 416 would be within the top 35 medical DRGs by volume in the inpatient prospective payment system. A surgical severe sepsis DRG made from severe sepsis cases in DRG 415 would be in the top 80 surgical DRGs by volume and have more cases than 150 other surgical DRGs.

Table 1: Comparison of relative size, resource use and outcome for cases with and without coded severe sepsis in the Septicemia DRGs from the FY 2005 MedPAR database

Current DRG	Severe Sepsis	Cases	LOS All	LOS Alive	Hospital Mortality	Mechanical Ventilation	Mean Standardized Charge
415	No	44,481	13.4	13.0	7.4%	7.1%	$56,612
415	Yes	9,067	17.4	18.8	31.3%	34.8%	$99,314
416	No	211,136	7.4	7.5	13.6%	4.5%	$25,730
416	Yes	65,841	7.7	9.4	40.3%	24.4%	$37,286

CMS Comments: "It is possible that the consolidated severity-adjusted DRG system that we are planning to adopt would better recognize the extensive resources that hospitals use to treat patients with severe sepsis."

Response: The Society of Critical Care Medicine commends CMS for recognizing the importance of severity of illness in accounting for resource use in patients both with and without severe sepsis. An examination of the supplemental FY 2004 MedPAR data file containing the consolidated severity adjusted DRG information showed that 76% of medical severe sepsis cases with organ support would be grouped into severity level 4 DRGs, and an additional 21% would be grouped into severity level 3 DRGs, leaving only 3% of cases in severity level 1 and 2 DRGs. Similar results come from looking at surgical cases where 97% of all severe sepsis cases would be in severity level 3 or 4 DRGs. This change would result in a 63% improvement in payment for medical cases of severe sepsis, but only a 12% increase for surgical severe sepsis cases.

The use of the APR-DRG base set of DRGs instead of the base CMS DRGs is the root cause of the imbalance in payment improvement between medical and surgical DRGs under the proposed new system. Surgical cases from MDC 05 (Circulatory disease) make up 45% of all surgical ICU cases and so surgical severe sepsis cases. Because the APR-DRG base set of DRGs do not account for the complexity of care (angioplasty without stenting, bare metal stents and drug-eluting stents are all in the same base DRG in the APR system), many far less resource intensive cases are grouped with more resource use intensive cases, reducing the average resource use associated with the base DRG.

Adding severity adjustment then recovers most of what was lost by not accounting for complexity of care with no real net benefit. Even though most of the problems with poor base DRGs are limited to MDC 05, since this MDC is responsible for nearly half of all surgical patients in intensive care units, it has significant repercussions resulting in only a 2% improvement in payment for surgical severe sepsis cases in MDC 05 and only 12% overall for surgical severe sepsis cases. **Further refinement of any proposed system for incorporation of severity of illness into the inpatient prospective payment system is required to recognize the**

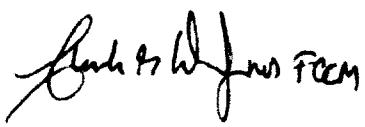
extensive resources that hospitals use to treat surgical patients with severe sepsis and overall.

Conclusion

We stand ready at the Society to assist CMS in analyzing the 2005 MedPAR data to best move severe sepsis cases into new DRGs. We strongly urge that these new DRGs be created for fiscal year 2007. The sweeping nature of the proposed severity-adjusted DRG system makes implementation of appropriate changes to recognize severe sepsis cases unlike in 2007. The data is available now that show that a significant volume of patients can be appropriately identified as having severe sepsis and that these patients are a clinically coherent group with similar resource utilization. Thus, these patients meet CMS's requirements for the creation of separate DRGs. We believe that creating these separate DRGs will lead to more appropriate payment to hospitals and better care for these patients.

If you have any questions concerning these comments, please contact Eric Chandler at the Society at 847-827-6866.

Respectfully submitted by,



Charles G. Durbin, Jr.,M.D., FCCM

160

PRC

1301 K Street, N. W. Suite 1100, East Tower, Washington, DC 20005
Barbara Levy, M.D., Co-Chair, Vincent Lucente, M.D., Co-Chair

Executive Board: Robert Harris, M.D., Steve Segal, M.D.,
G. Willy Davila, MD, Edward Stanford, M.D.,

June 12, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: CMS-1488-P - Medicare Program; Proposed Changes to the Hospital IPPS and FY 2007 Rates

Dear Dr. McClellan:

The Prolapse Repair Coalition (PRC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Medicare hospital inpatient prospective payment system (HIPPS) proposed rule for fiscal year 2007. The PRC is dedicated to raising awareness, particularly among national healthcare policy makers, of the critical importance of pelvic health and to promote education about pelvic prolapse. By dispelling myths and misunderstandings, the PRC is committed to improving the quality of life for women with pelvic prolapse by expanding access to new surgical therapies. Since its inception, the PRC has been committed to raising awareness of pelvic prolapse by promoting and expanding patient, public, and professional education; promoting advocacy efforts; and strengthening the voice of the pelvic prolapse community. The PRC is a broad-based coalition representing leading obstetric, urology, and gynecology healthcare professionals as well as the major industry leaders involved with developing innovative technologies used to treat pelvic prolapse. The PRC provides a forum where all critical stakeholders share viewpoints and reach consensus on major healthcare policy and reimbursement matters impacting prolapse repair.

The PRC commends CMS for striving to establish more appropriate Medicare payment for hospital inpatient treatment and embarking on an overhaul of the IPPS/DRG system. Our comments and recommendations are outlined and discussed below.

I. SUMMARY

Two major reforms related to diagnosis related groups ("DRGs") are being proposed by CMS. The first reform would base the DRG relative weights on estimated hospital costs rather than charges (referred to as HSRVcc weights) while the second reform calls for adjusting the DRG system to account for patient severity. We support CMS's decision to implement more appropriate DRG payment and our recommendations and comments are outlined below.

- ***Implement cost-base and severity of illness adjustments in FY 2008***. We agree with CMS' proposal to implement cost-based weights together with the DRG severity of illness adjustments. Hospitals, however, may need additional time to make such adjustments. Therefore, we recommend that CMS delay implementation of any modified cost-based weighting system until 2008 and implement the DRG weight changes together with appropriate DRG patient severity of illness adjustments at that time.

- ***Cost based weight changes must ensure patient access to pelvic prolapse treatments***.
To ensure appropriate hospital payment, CMS may wish to consider alternatives to the national hospital cost-estimate methodology. One alternative is the development of cost-based weights calculated using hospital-specific aggregate cost-to-charge ratios, rather than national average cost centers.

Another alternative is the cost-based weighting system that CMS uses for the hospital outpatient prospective payment system. If CMS does adopt HSRVcc weights, it should work to ensure the accuracy of the underlying data.

- ***Support patient severity of illness adjustments and technology adjustments***. The PRC supports DRG reforms designed to account for patient severity of illness as well as DRG reforms that take into account surgical technology and treatment variables. However, we recommend that CMS implement a method that appropriately recognizes surgical technologies that represent increased complexity and resources, but not necessarily greater severity of illness.

- ***Recommend new DRGs for pelvic prolapse with severity adjustments for 2007***. CMS should consider adjustment of the current DRG 356 Female Reproductive System Reconstructive Procedures to better reflect clinical coherence within the DRG of the procedures related to maintaining reproductive health. To accomplish this, we recommend creating four new clinically similar DRGs for procedures intended to repair pelvic floor defects that cause urinary incontinence. These new DRGs would be available to accommodate new ICD-9-CM codes being proposed for the September 28-29, 2006 ICD-9-CM Coordination and Maintenance Committee meeting that distinguish between pelvic prolapse reconstruction procedures that involve grafts and/or prostheses from those procedures that do not involve grafts or prosthetic implants.

The PRC is currently working to finalize its request for new ICD-9-CM procedure codes which will more closely track and reflect the granularity and specificity of the CPT codes for pelvic floor prolapse procedures. For example, in addition to the proposed new ICD-9 codes listed below, the PRC is examining codes for the following:

- Cystocele, rectocele repair with enterocele repair with and without mesh and
- Intraperitoneal versus extraperitoneal vault suspension.

The creation of these new ICD-9 procedure codes will allow hospitals to collect data specifically on the cases that involve a graft or prosthetic implant. The new DRGs with current and proposed new procedure codes are listed below. These proposed DRGs are structured the same as those DRGs that encompass procedures for the treatment of burns which distinguishing between those that use grafts and those that do not involve grafts.

Proposed New DRGs

XX1 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect without Graft or Prosthesis without CC

- 70.50 Repair of Cystocele and Rectocele (without graft or prosthesis)
- 70.51 Repair of Cystocele (without graft or prosthesis)
- 70.62 Vaginal reconstruction (without graft or prosthesis)
- 70.77 Vaginal suspension and fixation (without graft or prosthesis)
- 70.79 Other repair of vagina (without graft or prosthesis)
- 70.8 Obliteration of vaginal vault (without graft or prosthesis)

YY1 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect without Graft or Prosthesis with CC

- 70.50 Repair of Cystocele and Rectocele (without graft or prosthesis)
- 70.51 Repair of Cystocele (without graft or prosthesis)
- 70.62 Vaginal reconstruction (without graft or prosthesis)
- 70.77 Vaginal suspension and fixation (without graft or prosthesis)

- 70.79 Other repair of vagina (without graft or prosthesis)
- 70.8 Obliteration of vaginal vault (without graft or prosthesis)

XX2 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect with Graft or Prosthesis without CC

- 70.5X Repair of Cystocele and Rectocele with graft or prosthesis
- 70.5X Repair of Cystocele with graft or prosthesis
- 70.6X Vaginal reconstruction with graft or prosthesis
- 70.7X Vaginal suspension and fixation with graft or prosthesis

YY2 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect with Graft or Prosthesis with CC

- 70.5X Repair of Cystocele and Rectocele with graft or prosthesis
- 70.5X Repair of Cystocele with graft or prosthesis
- 70.6X Vaginal reconstruction with graft or prosthesis
- 70.7X Vaginal suspension and fixation with graft or prosthesis

Keeping the current DRG system, albeit refined, would enable CMS to would build upon the improvements that have been made in the DRG structure in recent years to account for new technologies.

II. DETAILED DISCUSSION

A. Proposed Changes to the DRG System

We share CMS's goal of providing appropriate payment for Medicare inpatient procedures. However as discussed below, the proposed changes are likely to have a significant impact on hospitals and patients. Therefore, we urge CMS to delay adopting sweeping DRG reforms in 2007 in order to implement the cost weighting changes together with the severity adjustments in 2008.

1. Proposed Change from Charges to Cost-Based HSRV Weights

CMS proposes to change the basis for the weights assigned to DRGs from hospital charges to estimated hospital costs, effective October 1, 2006. CMS refers to this weighting system as the hospital-specific relative value cost center, or HSRVcc methodology. The adoption of the HSRVcc weights is projected to decrease payment for some surgical DRGs. In light of the proposed impact on patient access, we urge CMS to consider alternatives to the HSRVcc weights that offer more appropriate reimbursement to hospitals for advanced surgical care. For example, CMS could use individual, hospital-specific aggregate cost-to-charge ratios, rather than national average cost centers or adopt cost-based weights similar to the system used under the hospital outpatient system.

We agree with MedPAC on the issue of implementation and recommend that cost-based weights should be implemented together with the patient severity of illness adjustments in 2008. This would also give CMS additional time to refine its DRG reform methodology and assure that the methodology results in payments that are as accurate as possible so that patient access to care is preserved. CMS could then move forward in 2008 with implementation of a cost-based weighting system together with patient severity of illness adjustments.

2. Severity of Illness Adjustments

The second proposed reform would adjust relative weights to reflect severity of illness among patients. Specifically, CMS suggests replacing the 526 current DRGs with about 861 DRGs adjusted for patient severity. As noted above, we support CMS's decision to implement adjustments to the DRG system

to better account for the severity of illness associated with individual patient cases. Adjustments for patient severity of illness are likely to result in more accurate hospital payments. However, we are concerned that the patient severity-adjusted DRG methodology does not accommodate accurate assignment of payment for complex surgical cases that involve the use of expensive surgical technology in patients that are not necessarily "sicker" i.e., have multiple co-morbidities.

One solution would be to overlay the patient severity of illness adjustments on the existing DRG structure, after implementing some interim adjustments for female reproductive procedures discussed below. Such an approach would have the advantage of building on the improvements that have been made in the DRG structure in recent years to account for new technologies. Another alternative would be to designate certain DRGs as device-dependent and ensure that the costs of such devices are appropriately reflected in the claim file data. We are confident that delaying implementation of the proposed DRG changes will provide CMS additional time to work with stakeholders over the next year to study modifications to the proposed patient severity of illness-adjusted DRG system and alternative systems that would account for the resources associated with complex surgical procedures.

B. DRGs: Genitourinary Reconstructive DRGs Needed in 2007

Adequate Medicare reimbursement is essential to assure that patients have access to clinically appropriate healthcare. Therefore, it is imperative that CMS implement adjustments regarding the procedure codes assigned to DRG 356 Female Reproductive System Reconstructive Procedures reflecting the clinical coherence of cases within the DRG that deal specifically with the major anatomy of the reproductive tract. Furthermore, we recommend creating four new DRGs for FY 2007 to reflect the clinical intent of these procedures which is to repair a pelvic floor defect for the purpose of treating a condition such as cystocele which causes discomfort and problems with emptying the bladder. Note, procedures that should be listed under DRG 356 should be related to reproductive function of a woman based on the title. For these reasons, the procedures listed under DRG 356 that involve urinary function and prolapse should be re-assigned.

Furthermore, the PRC in partnership with other organizations and professional coders will be submitting an application for the September 28-29, 2006 meeting of the ICD-9-CM Coordination and Maintenance Committee with several options for the committee to consider regarding ICD-9 procedure coding for surgical interventions that distinguish between pelvic prolapse reconstruction procedures that involve grafts and/or prostheses and those procedures that do not involve grafts or prosthetic implants. We believe that the current lack of systematic procedure coding that reflects the use of grafts and prosthetic implants is negatively impacting reimbursement rates to hospitals and is also hindering CMS in its ability to identify these cases in its MedPAR data for assignment of appropriate payment.

We believe it is important to make these DRG refinements now, for FY 2007, allowing for any new or revised ICD-9-cm procedure codes to then be assigned to these new DRGs starting in FY 2008. Also, these revisions would be in place and available to be part of the process regarding severity indexing in FY 2008.

Proposed New DRGs

XX1 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect without Graft or Prosthesis without CC

- 70.50 Repair of Cystocele and Rectocele (without graft or prosthesis)
- 70.51 Repair of Cystocele (without graft or prosthesis)
- 70.62 Vaginal reconstruction (without graft or prosthesis)
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- 70.8 Obliteration of vaginal vault (without graft or prosthesis)

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- 70.50 Repair of Cystocele and Rectocele (without graft or prosthesis)
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- 70.8 Obliteration of vaginal vault (without graft or prosthesis)

XX2 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect with Graft or Prosthesis without CC

- 70.5X Repair of Cystocele and Rectocele with graft or prosthesis
- 70.5X Repair of Cystocele with graft or prosthesis
- 70.6X Vaginal reconstruction with graft or prosthesis
- 70.7X Vaginal suspension and fixation with graft or prosthesis
- 70.8X Obliteration of vaginal vault with graft or prosthesis

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- 70.5X Repair of Cystocele and Rectocele with graft or prosthesis
- 70.5X Repair of Cystocele with graft or prosthesis
- 70.6X Vaginal reconstruction with graft or prosthesis
- 70.7X Vaginal suspension and fixation with graft or prosthesis
- 70.8X Obliteration of vaginal vault with graft or prosthesis

We appreciate your attention to our comments and would be pleased to provide additional information and meet with you and your staff to discuss any of these issues in greater detail.

Sincerely,

Barbara Levy, M.D.
Co-Chair

Vicent Lucente

Vicent Lucente, M.D., M.B.A.
Co-Chair, Prolapse Repair Coalition
Medical Director, The Institute for Female Pelvic Medicine and Reconstructive Surgery

G. Willy Davila, MD
Chairman, Department of Gynecology
Head, Section of Urogynecology and Reconstructive Pelvic Surgery
Cleveland Clinic Florida
Member PRC Executive Board
email: davilag@ccf.org

cc: PRC Members via email only

161

Grandview Medical Center

Kettering Medical Center Network

NETWORK FACILITIES

Grandview Hospital
405 W. Grand Avenue
Dayton, Ohio 45405
(937) 226-3200

Southview Hospital
1997 Miamisburg-
Centerville Road
Centerville, Ohio 45459
(937) 439-6000

Charles F. Kettering Memorial Hospital
3535 Southern Boulevard
Kettering, Ohio 45429
(937) 298-4331

Sycamore Hospital
2150 Leiter Road
Miamisburg, Ohio 45342
(937) 866-0551

Kettering Hospital Youth Services
5350 Lamme Road
Dayton, Ohio 45459
(937) 534-4600

Kettering College of Medical Arts
3737 Southern Boulevard
Kettering, Ohio 54529
(937) 395-8601

Sycamore Glen Retirement Community
317 Sycamore Glen Drive
Miamisburg, Ohio 45342
(937) 866-2984

GRANDVIEW SERVICES & FACILITIES

Victor J. Cassano Health Center

Corwin M. Nixon Community Health Center

Dayton Sports Medicine Institute

Grandview Center for Circulatory Disorders and Wound Treatment

The Grandview Foundation

Charles H. Huber Health Center

Joslin Diabetes Center affiliate at Southview Hospital

Preble County Medical Center

Southview Hospital Maternity Center

Sycamore Women's Center

June 7, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: **Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule**

Dear Dr. McClellan:

On behalf of Southview Hospital, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the FY'07 Medicare Inpatient Prospective Payment System (IPPS) published in the April 25, 2006 *Federal Register*. Given the complexities of CMS' proposal to revise the diagnosis-related group (DRG) system and the magnitude of impact this could have on our Southview Hospital, we are writing to urge a one-year delay in implementing these policy proposals.

CMS proposes to move from the historical charge-based DRG system to a cost-based system and to implement hospital-specific relative weights by October 1, 2006. CMS also proposes modifying the DRG classification system to account for differences in patient severity and allow for a payment amount that more closely tracks the cost of providing care. In its proposal, CMS states that it would replace the current 526 DRGs with either the proposed 861 consolidated severity-adjusted DRGs by FY'08 or a similar system that accounts for the level of patient severity, developed in response to public comments that it receives.
Southview Hospital supports meaningful improvement to Medicare payments for inpatient services and applauds the tremendous effort CMS has put forth to devise a

DRG system that more accurately reflects the costs of providing inpatient services. I recognize that your agency has taken these steps to make payments fairer to hospitals and to assure beneficiary access to services in the most appropriate setting. In the proposed rule, CMS seeks input on the proposed methodologies and solicits alternatives to the consolidated severity-adjusted DRG model. While we welcome the opportunity to work with CMS and other stakeholders in ensuring that any system implemented accomplishes the stated goals, we are extremely concerned with the tight timeline provided for developing comments and the implementation dates outlined in the proposal. Restructuring the DRG system as proposed in the rule would represent the most significant policy change to the IPPS since its inception. A change of this magnitude warrants a thoughtful and thorough review by hospitals, a task not easily accomplished during a 60-day comment period, given the complexity of the proposals.

As such, we strongly urge CMS to delay implementing both the proposed DRG reclassification and the changes to the relative weights until FY'08. The additional time will allow Southview Hospital and other hospitals to more thoroughly evaluate the proposals and offer constructive feedback to your agency.

Again, thank you for the opportunity to share our comments on the DRG provisions of the proposed IPPS rule.

Sincerely,

Gregory C. Henderson

Gregory C. Henderson, SEO
Southview Hospital Administration

162

NATIONAL ASSOCIATION of PUBLIC HOSPITALS and HEALTH SYSTEMS
1301 PENNSYLVANIA AVENUE, NW, SUITE 950, WASHINGTON DC 20004 | 202.585.0100 | FAX 202.585.0101

June 12, 2006

Dr. Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 443-G
200 Independence Avenue, SW
Washington, D.C. 20201

Ref: CMS-1488—P — Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates; Proposed Rule.

Re: DRG Reclassifications; EMTALA; Resident Time Spent in Non-patient Care Activities as Part of Approved Residency Programs; Outlier Payments; Health Information Technology; Hospital Quality Data; Value-Based Purchasing

Dear Dr. McClellan:

The National Association of Public Hospitals and Health Systems (NAPH) appreciates the opportunity to submit comments on the above-captioned Proposed Rule.[1] NAPH represents more than 100 metropolitan area safety net hospitals and health systems. Our members are deeply reliant on government-sponsored health programs. Approximately 71 percent of our revenues come from government sources, including Medicare, Medicaid, and local subsidies. Approximately 40 percent of the inpatient services provided by NAPH members is to Medicaid recipients and another 21 percent is provided to Medicare patients. Another 23 percent is to uninsured patients. NAPH members provide critical inpatient services with NAPH hospitals averaging 2.5 times as many inpatient admissions as the hospital industry average.

NAPH members also provide certain specialized services essential to their entire communities, such as emergency and trauma care, burn care, and neonatal intensive care. Our members are multifaceted institutions, often operating facilities at multiple sites and frequently serving as major training centers for medical residents and interns. Because of all of these characteristics, the proposed changes would significantly impact day-to-day operations of NAPH members.

[1] 71 Federal Register 23996 (May 25, 2006). Hereinafter "Proposed Rule."

Our detailed comments related to the Proposed Rule are attached. In summary, NAPH urges CMS to consider the following recommendations:

- NAPH supports CMS' policy goal to increase the accuracy of current IPPS payment methodologies. Such accuracy is critical to the financial stability of safety net providers who provide care without regard to the relative profitability of IPPS payments. In order to ensure the most accurate system possible, we encourage CMS to validate Hospital Specific Relative Value (HSRV) weighting using hospital cost data and seek further provider involvement in the process of developing the new severity-adjusted DRGs, paying particular attention to DRGs related to mental health services, which have been underpaid by the Medicare program for many years. Finally, to ensure payment accuracy, we urge CMS to instruct Medicare fiscal intermediaries to capture all diagnosis and procedures codes available under HIPAA electronic transaction standards.

- NAPH strongly supports CMS' proposal to apply Emergency Medical Treatment and Labor Act (EMTALA)[2] transfer requirements to hospitals without dedicated emergency departments. We strongly concur with CMS that EMTALA requires that all hospitals with the capability to accept EMTALA transfers do so regardless of whether the facility has a dedicated emergency department. We also urge CMS to more closely study emergency transfer patterns of affiliated hospitals, and, if appropriate, prohibit through regulation the selective transfer of patients based on insurance status. In addition, we also request that CMS establish through regulation a minimum threshold of on-call coverage to ensure that hospitals fulfill their EMTALA obligations to provide emergency screening and stabilization services to all patients.

- NAPH urges CMS to rescind its clarification in the Proposed Rule related to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

- NAPH opposes raising the outlier threshold and supports the American Hospital Association's (AHA's) recommendation to utilize a methodology that incorporates both *cost* inflation and *charge* inflation in calculating the outlier threshold. We believe the use of more than one indicator will make the threshold calculation more accurate and reliable. To account for the unspent outlier payments and attendant understated standardized amounts, NAPH urges CMS to retroactively adjust IPPS payments.

- NAPH believes that CMS has broad statutory authority to encourage and facilitate widespread adoption of health information technology (HIT) through broad federal support such as a comprehensive "Hill-Burton HIT Initiative." Safety-net providers that receive a

[2] The Consolidated Omnibus Budget Reconciliation Act of 1985, P.L. 99-272.

significant portion of their revenue through federal health care dollars and that operate with limited resources should be one of the primary recipients of federal HIT funding in particular because low income and indigent patients treated by the safety net are more likely to directly benefit from HIT reforms than other patient groups. NAPH supports HIT demonstration projects targeted at building an interoperable, national network of safety net providers.

- NAPH joins the AHA in urging that CMS require that hospitals only *prospectively* submit newly expanded quality measures. Thus, we request that CMS require hospitals seeking a full market basket update to start submitting the relevant data for all 21 measures for patients discharged beginning on or after July 1. We also strongly urge CMS to review on a case by case basis any incidence where a hospital's payment would be put in jeopardy as a result of the validation process.

- Finally, with regard to the development of pay-for-performance measures and value-based purchasing systems, CMS should ensure such metrics include quantification of the disparities in care experienced by patients of different races, ethnicities, and socioeconomic backgrounds

NAPH appreciates the opportunity to submit these comments on the Proposed Rule. If you have any questions about these comments, please contact Frederick Isasi at (202) 624-3969.

Sincerely,

Larry S. Gage
President

COMMENTS ON THE FY 2007 INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS) PROPOSED RULE

DRG Reclassifications

NAPH supports CMS' policy goal to improve the accuracy of current IPPS payment methodologies to better reflect the actual cost of providing care. Such accuracy is critical to ensuring the greatest possible efficiency in Medicare program. Moreover, such accuracy is critical to the financial stability of safety-net providers, who, because of their mission, provide care without regard to the profitability of IPPS payments.

The proposed DRG changes include a shift from a charge-based methodology to a hospital-specific, relative-value (HSRV) cost based weighting system and a new DRG system to better reflect patients' severity of illness. We encourage CMS to validate HSRV weighting using hospital cost data before implementing the proposed changes.

Furthermore, we urge CMS to seek further provider involvement in the process to consolidate 1,258 All-Patient Refined (APR) DRGs to develop the proposed 861 severity-adjusted DRGs. We are particularly concerned about consolidations related to obstetrics and psychiatric care services, which are critically important to safety net hospitals and, in the case of psychiatric care, have been historically underpaid by the Medicare IPPS system. Inadequate Medicare payment for inpatient mental health services has contributed to a critical shortage of mental health beds. **We urge CMS to ensure that the new severity-adjusted DRGs accurately reflect provider cost in all aspects of inpatient care. Furthermore, we urge CMS to pay particular attention to DRGs related to mental health services, which have been underpaid by the Medicare program for many years.**

Finally, we join the American Hospital Association (AHA)[3] in raising concerns that CMS' DRG GROUPER does not use all diagnoses and procedures that affect a patient's severity of illness and/or the resources utilized. The current DRG GROUPER only considers nine diagnoses and up to six procedures. Hospitals submit claims to CMS in an electronic format. The Health Insurance Portability and Accountability Act of 1996 (HIPAA)[4] electronic transaction 837i standard allows up to 25 diagnoses and 25 procedures to be entered by providers. Many fiscal intermediaries (FIs) are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the GROUPER to assign a DRG.

Capturing all diagnoses and procedures meeting the definitions of reportable secondary diagnoses and procedures will provide a more complete picture of patient complexity. As CMS considers

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[3] Letter from Mr. Rick Pollack, Executive Vice President, American Hospital Association to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 8, 2006).
[4] Pub. L. No. 104-191.

methodologies for refining the patient classification system, the number of secondary diagnoses may be an important factor in determining differences in patient characteristics. This is particularly true of patients with many chronic illnesses that add to the complexity of treating them. **To ensure payment accuracy, we urge CMS to instruct Medicare FIs to capture all diagnosis and procedures codes available under the HIPAA electronic transaction standards.**

EMTALA

NAPH strongly supports CMS' proposal to apply of Emergency Medical Treatment and Labor Act (EMTALA)[5] transfer requirements to hospitals without dedicated emergency departments. EMTALA was enacted in reaction to widespread reports in the 1980s of uninsured patients being denied emergency medical care and being "dumped" on safety net providers. When enacted, EMTALA was designed to ensure that all patients would receive emergency screening and stabilization services regardless of their insurance status or ability to pay.

As the largest providers of care to uninsured and underinsured patients, this issue is particularly salient to NAPH members, who provide healthcare services to all individuals, regardless of insurance status or ability to pay. Twenty-one percent of NAPH members' costs are uncompensated as compared to 5.5 percent of costs for hospitals nationally. In 2003 (the most recent data available), the uncompensated care provided by 85 NAPH members accounted for almost one quarter of the uncompensated hospital care provided throughout the country. NAPH members operate some of the busiest emergency departments in the country, and in many communities NAPH members are the primary source of emergency medical services for low-income and uninsured patients

NAPH strongly agrees with the statement in the Proposed Rule that the EMTALA mandate to accept transfers of patients applies to hospitals without dedicated emergency departments.[6] While such facilities may not routinely receive patients seeking emergency care, as Medicare participating hospitals, they should be held to the same standard as other hospitals and ensure that they accept transfer patients for whom they have the specialized capacity to treat. Such a policy also clearly fulfils the intention of EMTALA to avoid patient "dumping" by ensuring that all Medicare participating hospitals' provide care to patients in need without regard to patients' ability to pay. **Thus, we strongly concur with CMS that EMTALA requires that all hospitals with the capability to accept EMTALA transfers do so regardless of whether the facility has a dedicated emergency department.**

In addition to this issue, our members report other fundamental problems with the manner in which EMTALA obligations are being met and urge CMS to address these problems. First, members report that general service hospitals with limited capabilities and others with limited

[5] The Consolidated Omnibus Budget Reconciliation Act of 1985, P.L. 99-272.
[6] See Proposed Rule at 24118.

capabilities may be selectively transferring insured patients to affiliated facilities and transferring uninsured patients to safety net hospitals. In the case of uninsured patients, members report that such transfers are taking place even when the safety net hospital is located at a greater distance from the transferring hospital. In such circumstances, the safety net hospital is precluded under EMTALA from denying the selective transfer request. **We urge CMS to more closely study emergency transfer patterns of affiliated hospitals, and, if appropriate, prohibit through regulation the selective transfer of patients based on insurance status.**

Similarly, NAPH members also express concern that current non-specific EMTALA on-call policies may permit hospitals to circumvent EMTALA obligations. As clarified in 2003, EMTALA requirements do not include specific on-call staffing requirements but rather allow hospitals to maintain on-call lists in a manner that best meet the needs of their patients and are in accordance with available resources. Because of their mission, safety net hospitals often are committed to providing the full scope of clinical services, and therefore on-call coverage, 24 hours / 7 days a week. In some instances, NAPH members report that safety net hospitals have become the only source of on-call specialty coverage for large metropolitan areas. NAPH members have reported a significant increase in the number of patients transferred to safety net facilities as a result of a lack of available on-call specialty physicians in other hospitals.

While NAPH appreciates that the 2003 generalized on-call requirements were designed to avoid setting an "unrealistically high burden for some hospitals," we believe that because of their general nature, these non-specific requirements may actually allow hospitals to circumvent EMTALA obligations by providing little or no on-call coverage. **We urge CMS to establish through regulation a minimum threshold of on-call coverage to ensure that hospitals fulfill their EMTALA obligations to provide emergency screening and stabilization services to all patients.** Such a recommendation would be supported by CMS' statement in the preamble to the 2003 final rule which stated their intention to, "continue to investigate [on-call policies] in response to complaints and...take appropriate action if the level of on-call coverage is unacceptably low."[7]

Resident Time Spent in Non-patient Care Activities as Part of Approved Residency Programs

NAPH joins the Association of American Medical Colleges (AAMC) in strongly opposing CMS' proposal to eliminate time spent by resident in "didactic activities" as counting towards in a hospitals' direct Graduate Medical Education (GME) or Indirect Medical Education (IME) Full

[7] "Medicare Program, Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions, Final Rule." 68 Fed. Reg. 53222 (September 9, 2003).

Time Equivalent (FTE) calculation.[8] *The Proposed Rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the FTE resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."*

This position is in stark contrast to CMS' position articulated as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty."[9] We concur with CMS' 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in GME is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

We urge CMS to rescind its clarification in the Proposed Rule related to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Outlier Payments

NAPH joins AHA in opposing the proposed increase in the outlier threshold, given that outlier payments over the last several years consistently have been less than CMS projected. [10] The proposed approach unfairly penalizes hospitals with outlier cases, which are already reporting losses from treating these high cost patients and will only have to expend more resources to reach the higher threshold.

By statute, Medicare provides extra payments for unusually high cost cases in order to limit hospitals' financial risk from extraordinary costs, and to diminish any financial incentive to avoid

[8] Letter from Jordan J. Cohen, M.D., President, the Association of American Medical Colleges to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 12, 2006).
[9] Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins (September 24, 1999).
[10] Letter from Mr. Rick Pollack, Executive Vice President, American Hospital Association to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 8, 2006).

Medicare patients with especially serious illnesses.[11] These outlier payments are made only if the DRG payment, plus IME and DSH payments, plus any payments for new technologies, plus some fixed-loss cost outlier threshold (set annually by CMS) is exceeded. As required by statute, CMS sets the fixed-loss cost outlier threshold at a level that ensures that outlier payments constitute between 5 to 6 percent of total operating DRG payments plus outlier payments.[12] Also required by statute, CMS reduces the average IPPS standardized amount to account for the estimated proportion of total DRG payments made to outlier cases.[13]

In the Proposed Rule, CMS sets the FY 2007 fixed-loss cost outlier threshold at $25,530, an increase of 8 percent from the FY 2006 threshold amount of $23,600. NAPH believes the proposed increase in the outlier threshold is ill-advised given that CMS has consistently over estimated the cost of outlier payments over the last few years and total outlier payments have accounted for less than the target amount of 5.1 percent of DRG payments. AHA estimates that CMS under spent the funds set aside for outliers by $3 billion between FYs 2004 and 2006.[14] AHA data also indicate that if CMS finalized the proposed threshold of $25,530, CMS will once again over estimate the expected cost of outlier payments and under spend by $319 million in FY 2007.[15]

An unwarranted policy that raises the outlier threshold unfairly penalizes hospitals already reporting losses from treating these high cost patients. This policy is further exacerbated because CMS does not propose to retroactively adjust outlier payments or, in the alternative, standardized amounts, to ensure that payments for FY 2005 and FY 2006 are equal to the target of 5.1 percent of total DRG payments.

NAPH opposes raising the outlier threshold and supports AHA's recommendation to utilize a methodology that incorporates both *cost* inflation and *charge* inflation in calculating the outlier threshold. We believe the use of more than one indicator will make the threshold calculation more accurate and reliable. To account for the unspent outlier payments and attendant decreases in standardized amounts, NAPH urges CMS to retroactively adjust IPPS payments.

Health Information Technology

NAPH views Health Information Technology (HIT) as critical to the evolution of the healthcare industry. In the Proposed Rule CMS has asked for comments on the statutory authority of the

[11] Social Security Act § 1886 (d)(5)(A).
[12] Social Security Act § 1886(d)(5)(A)(iv).
[13] Social Security Act § 1886(d)(3)(B).
[14] Proposed Rule, 70 Fed. Reg. 23470.
[15] See Letter from Mr. Rick Pollack, Executive Vice President, American Hospital Association to Dr. Mark McClellan, Administrator, Centers for Medicare and Medicaid Services (June 8, 2006).

agency to facilitate HIT reforms and for general comments related to the agency's potential HIT efforts.

We believe that CMS has broad statutory authority provided under the Medicare Modernization Act (MMA) of 2003; the Deficit Reduction Act (DRA) of 2005; the Labor, HHS, Education FY2006 Appropriations bill,[16] and other federal laws to encourage and facilitate widespread adoption of HIT by the U.S. healthcare industry. NAPH believes that HIT has special significance to safety-net providers and urges the inclusion of the following concepts in CMS efforts to develop and promote a national HIT infrastructure.

HIT reform requires broad federal support such as a comprehensive "Hill-Burton HIT Initiative." HIT reforms represent enormous capital expenditures on the part of hospitals, health systems, and other providers. **NAPH supports the creation of comprehensive federal funding to implement HIT reform modeled after the Hill-Burton Act of 1946. Similar to Hill-Burton, the HIT funding should include federal grant programs as well as low-interest loans in exchange for an agreement on the part of participants to provide free or reduced cost medical services to low-income and uninsured patients.**

Safety net providers that receive a significant portion of their revenue through federal health care dollars and that operate with limited resources should be one of the primary recipients of federal HIT funding. Much of the health care provided by the safety net is financed through federal programs such as Medicare and Medicaid. At the same time these safety net providers are often operating with greatly limited resources and without the excess revenue necessary to finance comprehensive HIT reform. For example, the average margin for NAPH members was 0.5 percent – significantly lower than the average hospital margin of 4.8 percent. **In order for the federal government to most effectively leverage federal dollars, HIT funding and attendant improvements in safety and efficiency should be targeted to safety net providers and others that are the primary recipient of federal health care dollars and in greatest need of such funding.**

Low income and indigent patients are much more likely to delay receiving and to lack continuity in their receipt of health care services. In addition, such patients may lack the resources of insured patients to negotiate the complexities of the health care system and advocate for their interests. HIT reforms more directly impact these patients by ensuring that their providers have accurate and up-to-date information regardless of familiarity of the provider with the patient or the ability of the patient to negotiate the health care system. **Thus, safety net providers should be one of the primary recipients of HIT funds because low income and indigent patients treated by the safety net are more likely to directly benefit from HIT reforms than other patient groups.**

[16] Respectively, Pub. L. 108-173; Pub. L. 109-171; and Pub. L. 109-149.

NAPH supports HIT demonstration projects targeted at building an interoperable, national network of safety net providers. **NAPH believes that the federal government should offer demonstration projects involving safety net providers toward the end goal of establishing a national, interoperable HIT infrastructure.** The demonstration should focus on establishing common standards to facilitate interoperability; using HIT as a tool to improve adherence to clinical guidelines and the tracking of clinical outcomes; improving data collection capabilities of providers to prepare them for pay for performance arrangements; and increasing consumer involvement in health care decision-making, particularly among vulnerable populations.

Hospital Quality Data

NAPH supports CMS continued efforts to improve healthcare quality through the Hospital Quality Initiative(HQI). The DRA expands quality reporting requirements for hospitals to qualify for a full market basket (MB) update to their IPPS payments. The Proposed Rule would require hospitals to report data on 21 measures included within the Hospital Quality Alliance (HQA). This requirement would be retroactive and include data related to patients discharged on or after January 1, 2006. Hospitals failing to submit data by August 15 for the first calendar quarter of 2006 would receive IPPS payments with an update of MB minus 2 percentage points. Hospitals that fail data validation tests for data submitted for the first three calendar quarters of 2005 would also lose the 2 percentage points from the MB update.

While NAPH strongly supports the HQI and CMS' other quality improvement efforts, we urge CMS to reconsider requiring retroactive submission of quality data. Such a policy would be both difficult and costly and require that hospitals reopen files from which data have already been abstracted, renegotiate agreements with the vendors who assist them in collecting and processing the required information, and resubmit information to the clinical data warehouse. **We join the AHA in urging that CMS require that hospitals only *prospectively* submit the newly expanded quality measures. Thus, we request that CMS require hospitals seeking a full MB update to submit the relevant data for all 21 measures for patients discharged beginning on or after July 1.**

Further, we agree with CMS that it is critical that the collected data be validated. The process used to validate the HQA data was reviewed by the General Accounting Office, which concluded that there was "a high overall baseline of accuracy," but recommended several changes to improve the validation process.[17]

NAPH joins the AHA in raising concerns about the current quality data validation process. We understand that CMS has begun to work to improve the process, so that it can be used to support

[17] "CMS Needs More Rigorous Methods to Ensure Reliability of Publicly Released Data." General Accounting Office. Report to the Committee on Finance, U.S. Senate (January 2006) at page 2. Available at: http://www.gao.gov/new.items/d0654.pdf

payment decisions. However, in the first three calendar quarters of 2005, the validation process did not have sufficient integrity to warrant hospital payments being withheld based on the validation results. At this juncture, we firmly believe that the problems with the validation process itself need to be resolved before any payment decisions are made solely on the basis of the contractor's work. **We strongly urge CMS to review on a case by case basis any incidence where a hospital's payment would be put in jeopardy as a result of the validation process. In such instances, CMS should allow the hospital to submit information showing that it made a good faith effort to supply the data warehouse with accurate information so that the public could be informed about the quality of its care. If the hospital has made a good faith effort, it should receive full payment regardless of whether the data are deemed accurate enough for public display.** Further, CMS should instruct its QIO data warehouse to accept any significant corrections so that the public can have a full and accurate picture of hospital quality.

Value-Based Purchasing

The development of future pay-for-performance measures and value-based purchasing systems should include measurement of disparities in care experienced by patients of different races, ethnicities, and socioeconomic backgrounds. Disparity in the provision of health care services has been a well-documented concern of many in the health care field for several years. **NAPH believes that any comprehensive assessment of quality tied to pay-for-performance measures must include measurements of the disparity in care experienced by patients of different racial, ethnic, and socioeconomic backgrounds.** Such measures should include the ability of health care providers to offer culturally and linguistically appropriate care as well as other measures of the difference in the quality of care received by patients of different backgrounds.

163

MassMEDIC
Massachusetts Medical Device Industry Council

June 12, 2006

The Honorable Mark B. McClellan. M.D, Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, DC 20201

RE: [CMS-1488-P], Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year (FY) 2007 Rates

Dear Dr. McClellan:

The Massachusetts Medical Device Industry Council (MassMEDIC) appreciates the opportunity to provide our comment letter regarding the Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year (FY) 2007 Rate.

INTRODUCTION

MassMEDIC, an organization of 330 manufacturers, suppliers, research institutions and academic health centers, promotes the unique interests of the Bay State's growing and vibrant medical device sector. Through a variety of programs, informational seminars, advocacy campaigns and other projects, MassMEDIC provides medical device manufacturers and suppliers with information on industry trends and regulatory policies, and creates forums that allow members to exchange ideas and information on issues affecting the industry.

MassMEDIC understands the importance of the proposed changes to the U.S. healthcare system and fully supports CMS's efforts to increase the accuracy of Medicare payment for hospital inpatient stays. However, the inpatient prospective payment system (IPPS) system is enormously complex and has the potential to dramatically impact millions of beneficiaries, and therefore, MassMEDIC believes that these proposed change are due a great amount of study and scrutiny by both CMS and the public before they can be implemented.

RECOMMENDATION

MassMEDIC recognizes the monumental effort that CMS had undertaken in a short period of time to develop the proposed rule as well as the wide-reaching and significant impact that these changes will have on the healthcare community. As CMS indicated in its April 12, 2006, press release, the proposed rule includes the "first significant revision of the inpatient PPS since its implementation in 1983". These changes are in fact so large that it is impossible for the relevant stakeholder groups to conduct adequate analyses of CMS's proposal, including the data source, assumptions and calculations that underpin the proposed rule, and to answer the questions raised by CMS about the proposed rule, in the allotted 60 day comment period.

As such, we are requesting that the implementation date for the IPPS transformation to be deferred by a minimum of one (1) year. This request will serve two purposes. First, it will provide the many varied impacted stakeholders the time necessary to properly conduct and complete their own impact analyses. These analyses and resulting comments will not only provide CMS with the perspectives of the patients, providers and manufacturers impacted by the proposed rule, but will also provide CMS with additional input and recommendation regarding the design and implementation of the proposed rule. The input of CMS's other partners in delivering quality patient care has always been valuable and vital to the rule-making process. However, that value is diminished if such input is based on insufficient analyses of incomplete data and inadequate consideration of impact brought about by a hurried attempt to implement markedly significant changes in a short timeframe.

Second, the deferred implementation of the proposed rule will provide CMS with sufficient time to consider concerns of the healthcare community, further study its own questions about the proposed rule, make the adjustments to the system necessary to improve the accuracy of the system and effectively implement a more accurate and equitable system.

IMPACT ON PROVIDERS AND PATIENT CARE

As with any major revision to a reimbursement system, the majority of the burden of the change will be felt by the providers and patients. CMS's own analysis of the proposed changes indicated as much as a 20-30% decrease in reimbursement for some DRGs.

Payment Impact from HSRVcc and Consolidated Severity Adjusted DRGs

CMS DRG V23.0	CMS DRG Description	Number of Cases	Percent Change in Relative Weight Due to HSRVcc	Percent Change in Discharge Weighted Average Weight Due to Consolidated Severity-Adjusted DRGs	Total Impact All Changes
556	PERCUTANEOUS CARDIOVASC PROC W NON-DRUG-ELUTING STENT W/O MAJ CV DX	46,504	-30.7%	13.6%	-21.2%
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	143,345	-30.0%	-4.1%	-32.9%
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG	89,477	-24.5%	4.2%	-21.3%
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG	121,084	-17.2%	-3.0%	-19.7%
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	41,538	-15.7%	7.3%	-9.6%
104	CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W CARDIAC CATH	19,406	-11.7%	-5.8%	-16.8%
552	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT W/O MAJOR CV DX	80,278	-11.5%	0.7%	-10.9%
548	CORONARY BYPASS W CARDIAC CATH W/O MAJOR CV DX	32,049	-11.0%	5.0%	-6.6%

Source: Federal Register, 42 CFR Parts 409, 410, et al.

An immediate reimbursement decrease of such dramatic proportions and over a range of DRGs will be administratively and financially burdensome to the hospitals that provide such care. As cited in the June 7, 2006 edition of the Pioneer Press, implantable cardioverter defibrillators (ICDs) cost approximately $31,800 per device. The proposed rule would reduce payment for implantation of this device to $23,755, an amount less that the cost of the device alone. Such a dramatic decrease in reimbursement has the very realistic unintended consequence of impacting availability of the care that beneficiaries receive at hospitals. This is just one example of the immediate and very concrete impact that the proposed changes would have on patients and providers should they be implemented as proposed.

The proposed changes have too far-reaching of an impact on Medicare beneficiaries to allow implementation without more in-depth review by the relevant stakeholder groups and more consideration by CMS.

DATA ISSUES

Data Lag

Currently, there is a two-year lag between the hospital claims that are used to calculate charge-based DRG weights and their year of implementation. By changing from a charge-based system to a cost-based system, CMS would increase this lag by an additional 1.5 years. A 3.5 year lag in data provides too much of a disparity when calculating reimbursement for critical healthcare procedures and technologies. As an association representing high-technology medical device manufacturers, we are particularly concerned that many of the new life-saving technologies that have become available to providers and patients in recent years would not be captured in the cost-based system for many years.

Any underpayment of these DRGs for up to 3.5 years is not sustainable in the high-paced and evolving field of medical technologies. By underpaying providers for so long, this proposed system in fact creates a disincentive to provide patients with the newest technologies. While advances in medical technologies will greatly improve patient care, a lag in appropriate reimbursement will force providers to be faced with the dilemma of losing money when using new technologies or using less expensive and potentially less effective technologies.

Data Quality

Hospital cost reports, on which the proposed DRG weights are calculated, were developed and used many decades ago when hospitals were generally reimbursed for providing care on a cost system. Since the implementation of the Medicare IPPS in 1983 and other prospective payment systems used by other payers, there have been few incentives for hospital providers to bill and code appropriately to ensure that all of their costs are captured. Any calculation using this data will not fully reflect the cost of providing care to patients.

A much larger effort must first be undertaken by CMS and the broader healthcare community to improve cost reporting to allow for future utilization of this data to calculate cost-based weights for DRGs.

IMPLEMENTATION PHASES

As written, the proposed rule suggests implementing the IPPS changes in two phases. The first phase implements the DRG weights based on hospital costs instead of hospital charges and would go into effect on October 1, 2006. The second phase would introduce some severity-adjusted DRG system in FY 2008.

MassMEDIC is concerned that the two-phase implementation approach will create tremendous changes in reimbursement at both the hospital- and patient/DRG- level which will create havoc for the providers. By CMS's own calculations, while the total impact of these two phases is significant in itself, the impact of each phase of the changes can be even greater, resulting in a dramatic decrease in payment in one year and a dramatic decrease in payment the second year, or vice versa. CMS should follow MedPAC's original intent in its *2005 Recommendations to Congress on Physician-Owned Specialty Hospitals* and, when appropriate, implement both phases of the changes together in order to minimize the impact to providers and patients.

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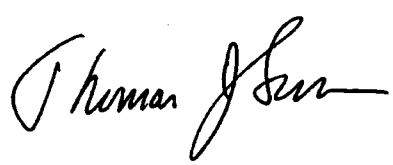
In summary, MassMEDIC encourages CMS to:

- Work with the public to understand and address their issues regarding the data used to develop the proposed rule, the implementation of the rule and the ultimate impact of such a rule on each stakeholder group.
- Defer the implementation of DRG weights based on hospital costs by at least one (1) year to allow for further examination and to address the issues and concerns about the proposal brought up by both CMS and the public.
- Couple the implementation of DRG weights based on hospital costs with the change to a severity-adjusted DRG system to avoid the potential for wide variances in payments if implemented separately.

Thank you for the opportunity to provide comment on the proposed rule. Should MassMEDIC be able to assist in this very important initiative in anyway, please do not hesitate to contact us at 617-414-1340.

Sincerely,



Thomas J. Sommer
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Providence Health & Services

June 12, 2006

Dr. Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Reference: CMS-1488-P; FY07 Hospital Inpatient Prospective Payment System Notice of Proposed Rulemaking, Federal Register April 25, 2006.

Dear Doctor McClellan:

Providence Health & Services is pleased to take this opportunity to provide you with our comments on the proposed rule implementing changes to the hospital inpatient prospective payment system for federal fiscal year 2007, published in the April 25, 2006 Federal Register.

Providence Health & Services (Providence) is a faith-based, non-profit health system that operates 29 acute care hospitals with 5,210 beds in Washington State, Oregon, California, Montana, and Alaska, along with freestanding long term care facilities, physician groups, home health agencies, assisted living, senior housing, PACE programs, and a health plan. In 2005 Providence Health & Services served 253,721 acute care admissions. Nearly thirty percent of our system's gross revenue is charged to the Medicare program.

The proposal advanced by the Centers for Medicare and Medicaid Services (CMS) represents the most significant change to the prospective payment system since its inception. Providence is supportive of the policy objective underlying the proposed changes to the payment methodology: Linking payments more closely to the costs which providers incur while taking into account very real differences in patient characteristics is a worthy goal. However, we have serious concerns about the proposed changes to the payment methodology and the associated implementation schedule: The proposed rule is exceedingly complex and its implications are at best difficult to discern although they appear to be profound. Consequently, Providence strongly urges CMS to take a more measured approach to implementation by delaying the major elements of this proposal while work continues to address the concerns outlined in the comments that follow. While we support your agency's efforts to improve the payment methodology and look forward to working with you to achieve that end, Providence is concerned that a rushed implementation will compromise the fundamental goals of improving access and quality of health care for all

Medicare beneficiaries. Our recommendations follow our analysis and comments on the proposed payment reforms.

PAYMENT METHODOLOGY REFORMS ("HSRV WEIGHTS" AND "SEVERITY OF ILLNESS")

As noted above Providence supports the policy objective advanced by CMS in this proposal. The ability of the payment methodology to better account for case-mix related variations in costs is a worthy goal. In order to achieve this outcome two fundamental and inter-related questions must be addressed:

1. What is the best methodology for assigning patients to specific classifications in order to take into account patient characteristics that can be reasonably expected to account for differences in costs?
2. Once patients have been grouped into the proper category, how can the costs of providing hospital inpatient services to this particular class of patients be properly determined?

Each of these questions is addressed in the proposed rule and our comments are intended to analyze the adequacy of the overall proposal in light of the proposed answers to these questions. However, each of these issues is interrelated and should not be answered independently of one another. To do so risks significant compromises to realization of the policy objective to link payments more closely to the costs which providers incur while taking into account very real differences in patient characteristics. For example, even if costs are properly identified but the patient classification methodology is inadequate then payments will be mal-distributed with the result of compromised access and possibly even quality. ***Consequently, there is a need for the agency to address each of these questions at the same time.*** This is especially important given the significant nature of each of the proposed changes.

Assigning Patients To Specific Classifications In Order To Take Into Account Patient Characteristics

Although the initial patient classification system has been modified over time to reflect changes in clinical practice and technology, its fundamental features have remained largely unchanged since the advent of the prospective payment system. In the proposed changes to the inpatient prospective payment system for FY06 CMS noted its intention to address the limitations of the current patient classification system to better account for severity of illness within a specific Diagnostic Related Group (DRG). Apart from those conditions where a patient may be assigned to a different DRG based upon the presence of a complication or comorbidity (CC), the system fails to reasonably account for variations in resource use and cost for patients with differing levels of severity within the same DRG. This problem has been well documented in the literature and has been the subject of several studies by the Medicare Payment Advisory Commission (MedPAC). Comments filed by Providence last year strongly supported the stated intention of CMS to make changes to the patient classification system. To that end Providence has been modeling the APR-DRG system over the past year. We have gained insights about the critical need for training for our staff in order to identify the increased number of diagnostic and

procedure codes necessary to make a proper assignment. Our experience has taught us that the changes required to implement this system go far beyond simply updating to a new software version of a GROUPER.

Notwithstanding our support for a shift to a better patient classification system such a move must not be undertaken without careful analysis because of its profound implications. This comment should not be construed as a simple provider concern about "winners and losers" under any proposed change: Providence is concerned about the impact of such a change on access to needed services by Medicare beneficiaries. Consequently it is imperative that analysis be conducted to demonstrate that any change – beyond just the mere proliferation of patient categories – actually enhances the predictive power of the overall payment system's ability to better account for case-mix related variations in cost. That analysis needs to be done in order to permit informed comments and to serve as the justification for the proposed change. This is not to argue against moving to a more refined model and as the foregoing comments indicate Providence has experimented with the APR-DRG system and finds it promising. However, this should not be a hasty move and it should be thoroughly analyzed before implementation proceeds. This is especially important in light of the fact that the data used for the preliminary modeling was truncated to nine diagnostic and procedure codes while the HIPAA 837i transaction standard permits 25 procedure codes and 25 diagnoses to be submitted. The responsibility of the agency to take a more measured approach is also critical given the fact that many payers, including numerous state Medicaid agencies, use Medicare's patient classification system as a basis for payment. The unintended consequences of this change are enormous and deserve careful analysis before proceeding.

Properly Determining the Costs of Providing Hospital Inpatient Services

If the prospective payment system is to achieve its objective of linking payments more closely to the costs that providers incur then there must be an acceptable methodology for determining costs for each case mix category. Under the current system CMS utilizes charge data in lieu of costs. In advancing this proposal CMS proposes an elaborate methodology to adjust charges to a proxy for costs and to weight payments accordingly. Briefly stated, the agency developed on a charge basis hospital-specific relative weights for each of ten cost centers and for each DRG. CMS then used these hospital-specific weights to calculate national DRG weights. These charge-based weights were "scaled" to a proxy for costs using the national cost-to-charge ratios (CCRs) for each cost center derived from cost reports as opposed to using hospital-specific CCRs at the claim level. CMS believes that this approach will remove the effect of different CCRs across departments within hospitals.

However, the proposed changes would further distort the estimation of accurate costs by combining multiple costs centers on hospital cost reports into ten CMS-designated cost centers. CMS would then determine ten national average cost-to-charge ratios for each of the designated costs centers. However, such ratios would not be weighted by each hospital's Medicare charges. This would allow very small hospitals to have just as much of an impact on the establishment of the national cost-to-charges ratios as hospitals with much larger Medicare volumes. These and other methodological issues seem reason enough to invest additional time and energy in the assessment and, as appropriate, further refinement of this proposed change. This is not to argue

against a policy direction that moves to utilizing cost data as opposed to charge data for establishing the relative weights used to set payment rates. However, as in the case of the proposed changes to the patient classification system this cost-finding methodology is a critical element of the payment system and must be carefully evaluated before proceeding.

Overall Recommendations and Conclusions

When any major payment change is under consideration it is easy to adopt a position based upon the re-distributional effects of the proposal. As a large health system some of our hospitals fare well under these changes as best we can model their effects while others face draconian reductions. Once the severity of illness measures are implemented many of the results change. We have also seen similar analyses based upon the particular scope of services provided by a hospital. Not surprisingly, some are advocating for implementation for only that part of the proposal that advantages their particular institutions. This is neither the approach taken by Providence nor does it serve as the rationale for the position that follows.

1. **First, the agency should adopt a position of "Do no harm."** There are profound consequences to the adoption of any major policy change of the magnitude suggested by this proposal. While there is a significant redistribution of payments among providers these changes translate into very important decisions about whether a provider continues to provide a particular service. Access to needed services by beneficiaries can be easily compromised - albeit unintentionally - as a result of payment changes. To understand these effects before committing to a course of action is essential. Until it can be validated that these changes enhance the predictive value of the payment methodology to better distribute payments on the basis of case-mix related variations in cost they should not be adopted.

   Recommendation: Because the "do no harm" test has not been met the proposed changes should not be implemented until they can be validated.

2. **The agency must address the severity of illness and cost-finding issues simultaneously.** Beyond enhancing the predictive value of the payment methodology the changes must ensure some level of predictability. The important interrelationship between assignment of patients into classifications that better explain resource use and cost and in turn how costs are determined and linked to payment cannot be overstated. It is somewhat analogous to adjusting the air and gas mix on a car's engine: They must be carefully balanced or the engine will not perform properly. Simply put, we cannot support efforts to better account for the costs of providing a service to a particular class of patients unless the changes to the patient classification system are implemented at the same time. Absent such an approach the policy objective of linking payments more closely to the costs which providers incur while taking into account very real differences in patient characteristics will not be met. For a provider's payment rate to significantly increase in one year only to be reduced the next year or to experience the reverse is both unnecessary and unwise to say nothing about its impact on beneficiaries. Staggered implementation will only serve to exacerbate the issues of transitioning to the new

system. The data in the impact table clearly suggests that implementing only one portion of the needed changes at a time will create many unintended consequences.

> **Recommendation: CMS should not implement either the change to the cost finding and weighting methodology or the patient classification system until they can be done simultaneously.**

3. **CMS must address the implementation issues by providing sufficient time for providers to adjust to any new payment system.** As Providence has found from its own experience these changes require both time and resources in order to be properly implemented. Even though many of the effects are known in the aggregate, software vendors will need to make information system changes and staff will need to be trained. This cannot be done in the typical sixty-day period between the publication of a final rule and its scheduled implementation. To mitigate these very real issues and to allow for a more thoughtful consideration of the very real long-term effects of any change of this magnitude, a transition methodology must be incorporated that blends the effects of any changes with the current system over a relatively short period of time.

> **Recommendation: CMS should adopt a three-year transition period to allow providers to implement these changes and to mitigate the dramatic rate redistributions that are suggested by the impact analysis provided by CMS. Similar to the agency's experience with other significant changes, a 25/75, 50/50, and 75/25 weighting factor between the new and old systems should be applied when calculating the rates for all providers (including new providers) during this three year, phase-in period. This period should also be used to evaluate the effects of these changes in order to ensure the beneficiary access to needed services is not compromised.**

Again, notwithstanding these conclusions Providence supports both the policy objective described above and the efforts of the agency to improve the payment system's ability to better account for severity of illness and to use better measures of cost – as opposed to charges - for establishing payment rates. Using the recommendations advanced by Providence will we believe achieve a better result than adopting the changes as proposed.

OTHER COMMENTS

There are four other areas of importance where Providence would offer comments for the agency's consideration prior to the adoption of the final rule: Outlier Methodology, EMTALA, Continued Designation of a Critical Access Hospital as a Necessary Provider, and Reporting of Quality Data. Our comment for each of these issues follows.

OUTLIERS Even with a more refined payment methodology Providence believes that an outlier mechanism is essential part of any payment system. To that end Providence has supported past initiatives advanced by CMS including efforts to eliminate the distortion caused by past

manipulation of this important provision by some providers who inflated their charges in order to maximize outlier reimbursement. While Providence supports the efforts of CMS to use a charge inflation methodology to eliminate the distortion that may have been caused by atypically data from 2003, we remained concerned that the methodology will continue to result in an inappropriately high outlier threshold. This is particularly apparent when one examines the difference between the amounts that CMS withholds from the "standardized pool" for outlier payments with the actual funds expended for this purpose. Last year CMS projected payments that would equal about 5.1 percent of total DRG payments but the amount actually spent appears to be about .47 percent less than the projected amount. In FY05 outlier payments represented only 3.8% of total payments or $1.15 billion less than the amount set aside. Again, we would encourage that an evaluation be conducted to examine the practicality and effects of a correction similar to the update forecast error adjustment. We are not advocating for adoption of such a methodology at this time but rather that an analysis be conducted.

EMTALA The EMTALA-related survey and certification issues – including enforcement – have proven to be problematic for the agency and providers alike. In this proposed rule CMS proposes two changes of interest to Providence. First Providence fully supports the modifications to the definition of "labor" found at 42 CFR 489.24(b). These provisions would allow qualified medical personnel such as a nurse-midwife to certify that a woman is in false labor to the extent that such a determination is within the scope of state practice laws and the hospital's medical staff bylaws. Second, Providence strongly supports changes advanced by CMS to require a hospital with a "specialized capability" to accept appropriate transfers regardless of whether it has a dedicated emergency department. Providence is supportive of this proposal and urges CMS to specifically extend this definition to include physician-owned, limited-service specialty hospitals under EMTALA even if they do not have a dedicated emergency department. Furthermore we would call upon the agency to issue guidance to require these facilities to have transfer agreements with community, full-service hospitals in order to address the very real issues associated with emergency transfers and to promote continuity of care.

CONTINUED DESIGNATION OF A CRITICAL ACCESS HOSPITAL (CAH) AS A NECESSARY PROVIDER Providence supported the regulatory proposal to allow CAHs to retain their designation as a necessary provider if they relocated after January 1, 2006. However, the interpretative guidelines later issued by the agency served to inappropriately broaden the scope beyond that of the regulation. As the National Rural Health Association (NRHA) has noted in its comments, the interpretative guidelines extend the relocation restrictions to all CAHs, not just necessary providers; establish a more stringent 75 percent requirement by requiring the CAH to serve 75 percent of the original families with incomes at less than 100 percent of the federal poverty level, serve at least 75 percent of the original Medicaid and Medicare beneficiaries, and bill at least 75 percent of the billing codes and volume for inpatient and outpatient services; and set overly prescriptive definitions of mountainous terrain and secondary roads than called for in the regulation. Providence encourages CMS to align the interpretive guidelines with the requirements of the codified regulations. We further support efforts to modify the existing regulations by developing a "safe harbor" for CAHs so they can retain their status as long as they move within 5 miles of the existing facility. We concur with NRHA's assessment that adoption of this alternative will "greatly

reduce the administrative burden for CMS, eliminate the uncertainty for CAHs, and is sufficient to assure that CAHs will continue to serve the same community."

REPORTING OF QUALITY DATA Consistent with provisions of the Deficit Reduction Act CMS has proposed to make a two-percentage point reduction to the market basket adjustment to any hospital that fails to comply with the quality data reporting requirements. Under the terms of the proposed rule, hospitals would be required to pledge to provide data on all twenty-one measures for patients discharged on or after January 1, 2006 in order to avoid this payment reduction. Providence fully supports the agency's efforts to make more robust hospital quality data available to the public. However, the practical effect of January 1st cut-off date is to require hospitals to re-open charts from which data has already been abstracted and at a cost that has not been previously negotiated in order to submit the enhanced data sets to the clinical data warehouse. We do not see an attendant benefit given these costs and would ask that CMS adopt a data reporting cut-off date on a prospective basis.

Thank you again for the opportunity to comment on these proposed changes. If you have any questions, please contact Chuck Hawley, Vice President of Government Affairs, at (206) 464-4237 or via e-mail at chuck.hawley@providence.org.

Sincerely,

John Koster MD

Dr. John Koster, M.D.
President/CEO
Providence Health & Services

165

AMS
Solutions for Life

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June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26.05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS -1488-P; Proposed Changes to the Inpatient Prospective Payment System for Fiscal Year 2007

Dear Dr. McClellan:

American Medical Systems ("AMS") appreciates the opportunity to comment on the Proposed Rule for the 2007 Medicare Inpatient Prospective Payment System (IPPS), CMS-1488-P.

AMS is a leader in medical devices and procedures to treat urological and gynecological disorders such as erectile dysfunction ("ED"), urinary incontinence, and menorrhagia. Although not life-threatening, these disorders can greatly affect one's quality of life and social relationships. As such, AMS recommends that the Centers for Medicare and Medicaid Services create four new DRGs for procedures intended to repair pelvic floor defects that cause urinary incontinence. These new DRGs would accommodate the new ICD-9-CM codes being proposed at the September 28-29, 2006 ICD-9-CM Coordination and Maintenance Committee meeting. The new ICD-9 codes are intended to distinguish between pelvic prolapse reconstruction procedures that involve grafts and/or prostheses from those procedures that do not involve grafts or prosthetic implants. Our comments are intended to ensure that IPPS payments for hospital stays where the principle surgical procedure is pelvic reconstruction where a graft or prosthetic implant is used support access for female Medicare patients to these procedures.

AMS is also a member of the Prolapse Repair Coalition ("PRC"). The PRC is a broad-based coalition representing leading obstetric, urology, and gynecology healthcare professionals as well as the major industry leaders involved with developing innovative technologies used to treat pelvic prolapse. The PRC provides a forum where all critical stakeholders share viewpoints and reach consensus on major healthcare policy and reimbursement matters impacting prolapse repair. AMS supports PRC's comments on the proposed rule for 2007 and wishes to emphasize the following points.

Our recommendations are summarized briefly below:

- ***Implement cost-base and severity of illness adjustments in FY 2008***. We agree with CMS' proposal to implement cost-based weights together with the DRG severity of illness adjustments. Hospitals, however, may need additional time to make such adjustments. Therefore, we recommend that CMS delay implementation of any modified cost-based weighting system until 2008 and implement the DRG weight changes together with appropriate DRG patient severity of illness adjustments at that time.

- ***Cost based weight changes must ensure patient access to pelvic prolapse treatments***. To ensure appropriate hospital payment, CMS may wish to consider alternatives to the national hospital cost-estimate methodology. One alternative is the development of cost-based weights calculated using hospital-specific aggregate cost-to-charge ratios, rather than national average cost centers. Another alternative is the cost-based weighting system that CMS uses for the hospital outpatient prospective payment system. If CMS does adopt HSRVcc weights, it should work to ensure the accuracy of the underlying data.

- ***Support patient severity of illness adjustments and technology adjustments***. The PRC supports DRG reforms designed to account for patient severity of illness as well as DRG reforms that take into account surgical technology and treatment variables. However, we recommend that CMS implement a method that appropriately recognizes surgical technologies that represent increased complexity and resources, but not necessarily greater severity of illness.

- ***Recommend new DRGs for pelvic prolapse with severity adjustments***. CMS should consider adjustment of the current DRG 356 Female Reproductive System Reconstructive Procedures to better reflect clinical coherence within the DRG of only those procedures performed on female organs that reflect an intent to maintain reproductive health. To accomplish this, we recommend creating four new DRGs that would be clinically similar for procedures intended to repair pelvic floor defects that cause urinary incontinence and would be available to accommodate new ICD-9-CM codes being proposed for the September 28-29, 2006, ICD-9-CM Coordination and Maintenance Committee meeting that distinguish between pelvic prolapse reconstruction procedures that involve grafts and/or prostheses from those procedures that do not involve grafts or prosthetic implants. The creation of these new ICD-9 procedure codes will allow hospitals to collect data specifically on the cases that involve a graft or prosthetic implant. The new DRGs with current and proposed new procedure codes are listed in the background section. These proposed DRGs are structured the same as those DRGs that encompass procedures for the treatment of burns which distinguishing between those that use grafts and those that do not involve grafts.

- ***Prior to implementing a cost based system of payments, CMS must provide a solution for charge compression***. Research is now available that supports much needed adjustments to offset charge compression. This research takes advantage of the detailed coding of supply charges by revenue center and the use of regression analysis to develop one set of CCR adjustments for each of the five supply sub-categories. We recommend that CMS review the analysis and Charge Compression Report and propose a solution for charge compression prior to implementing any proposed cost based system.

DETAILED DISCUSSION

Proposed Changes to the DRG System

We share CMS's goal of providing appropriate payment for Medicare inpatient procedures. However as discussed below, the proposed changes are likely to have a significant impact on hospitals and patients. Therefore, we urge CMS to delay adopting sweeping DRG reforms in 2007 in order to implement the cost weighting changes together with the severity adjustments in 2008.

Proposed Change from Charges to Cost-Based HSRV Weights

CMS proposes to change the basis for the weights assigned to DRGs from hospital charges to estimated hospital costs, effective October 1, 2006. CMS refers to this weighting system as the hospital-specific relative value cost center, or HSRVcc methodology. The adoption of the HSRVcc weights is projected to decrease payment for some surgical DRGs. In light of the proposed impact on patient access, we urge CMS to consider alternatives to the HSRVcc weights that offer more appropriate reimbursement to hospitals for advanced surgical care. For example, CMS could use individual, hospital-specific aggregate cost-to-charge ratios, rather than national average cost centers or adopt cost-based weights similar to the system used under the hospital outpatient system.

We agree with MedPAC and Chairman Thomas on the issue of implementation and recommend that cost-based weights should be implemented together with the patient severity of illness adjustments in 2008. This would also give CMS additional time to refine its DRG reform methodology and ensure that the methodology results in payments that are as accurate as possible so that patient access to care is preserved. CMS could then move forward in 2008 with implementation of a cost-based weighting system together with patient severity of illness adjustments.

Severity of Illness Adjustments

The second proposed reform would adjust relative weights to reflect severity of illness among patients. Specifically, CMS suggests replacing the 526 current DRGs with about 861 DRGs adjusted for patient severity. As noted above, we support CMS's decision to implement adjustments to the DRG system to better account for the severity of illness associated with individual patient cases. Adjustments for patient severity of illness are likely to result in more accurate hospital payments. However, we are concerned that the patient severity-adjusted DRG methodology does not accommodate accurate assignment of payment for complex surgical cases that involve the use of expensive surgical technology in patients that are not necessarily "sicker," i.e., have multiple co-morbidities.

One solution would be to overlay the patient severity of illness adjustments on the existing DRG structure, after implementing the interim adjustments for female reproductive procedures discussed below. Such an approach would have the advantage of building on the improvements that have been made in the DRG structure in recent years to account for new technologies. Another alternative would be to designate certain DRGs as device-dependent and ensure that the costs of such devices are appropriately reflected in the claim file data. We are confident that delaying implementation of the proposed DRG changes will provide CMS additional time to work with stakeholders over the next year to study modifications to the proposed patient severity of illness-adjusted DRG system and alternative systems that would account for the resources associated with complex surgical procedures.

Need to fix Charge Compression in a Cost based Payment System

Although evidence of the effect of charge compression is not new, research that could support an adjustment to offset charge compression was not previously available. Research just completed now presents a solution. It takes advantage of the detailed coding of supplies charges by revenue center on Medicare claims data to split the single cost-report CCR into separate CCRs for each supplies sub-category. Five supplies sub-categories are used: general supplies, implantables, sterile supplies, pacemakers (and defibrillators), and all other supplies. The division is based on a strong statistical association between the mix of supplies charges (by revenue center) in a hospital and the overall supplies CCR in a hospital. By pooling the information from all hospitals, research using regression analysis was able to develop one set of CCR adjustments reflecting national average CCRs for each of the five supplies sub-categories. Next, the research applied this national-average set of adjustments to each hospital (combining the adjustments with each hospital's actual supplies CCR), and inserted a "decompressed" estimate of cost on each MedPAC record.

The research found a strong and statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's overall average CCR for supplies. Hospitals with a higher share of charges in the pacemaker and implantable device revenue centers (0275, 0278) have higher supplies CCRs. Therefore, we recommend that CMS examine the research and consider using the coefficients from a regression model such as this to develop a data-driven adjustment for creating CCRs for sub-categories of supplies including surgical implants such as those used in prosthetic urology procedures and prolapse repair procedures.

DRGs: Genitourinary Reconstructive DRGs

Adequate Medicare reimbursement is essential to assure that patients have access to clinically appropriate healthcare. Therefore, it is imperative that CMS implement adjustments regarding the procedure codes assigned to DRG 356 Female Reproductive System Reconstructive Procedures reflecting the clinical coherence of cases within the DRG that deal specifically with the major anatomy of the reproductive tract. Furthermore, we recommend creating four new DRGs for FY 2007 to reflect the clinical intent of these procedures which is to repair a pelvic floor defect for the purpose of treating a condition such as a cystocele which causes discomfort and problems with emptying the bladder. The procedures that we

would propose be listed under DRG 356 would have the intent of ensuring the reproductive function of a woman versus the intent of many of the procedure codes currently listed under DRG 356 which is to maintain proper urinary function.

Furthermore, the AMS will coordinate with the PRC as it submits an application for the September 28-29, 2006, meeting of the ICD-9-CM Coordination and Maintenance Committee with several options for the committee to consider regarding ICD-9 procedure coding for surgical interventions that distinguish between pelvic prolapse reconstruction procedures that involve grafts and/or prostheses and those procedures that do not involve grafts or prosthetic implants. We believe that the current lack of systematic procedure coding that reflects the use of grafts and prosthetic implants is negatively impacting reimbursement rates to hospitals and is also hindering CMS in its ability to identify these cases in its MedPAC data for assignment of appropriate payment.

We believe it is important to make these DRG refinements now, for FY 2007, allowing for any new or revised ICD-9-cm procedure codes to then be assigned to these new DRGs starting in FY 2008. Also, these revisions would be in place and available to be part of the process regarding severity indexing in FY 2008.

Proposed New DRG Structure:

XX1 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect without Graft or Prosthesis without CC

- 70.50 Repair of Cystocele and Rectocele (without graft or prosthesis)
- 70.51 Repair of Cystocele (without graft or prosthesis)
- 70.62 Vaginal reconstruction (without graft or prosthesis)
- 70.77 Vaginal suspension and fixation (without graft or prosthesis)
- 70.79 Other repair of vagina (without graft or prosthesis)
- 70.8 Obliteration of vaginal vault (without graft or prosthesis)

YY1 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect without Graft or Prosthesis with CC

- 70.50 Repair of Cystocele and Rectocele (without graft or prosthesis)
- 70.51 Repair of Cystocele (without graft or prosthesis)
- 70.62 Vaginal reconstruction (without graft or prosthesis)
- 70.77 Vaginal suspension and fixation (without graft or prosthesis)
- 70.79 Other repair of vagina (without graft or prosthesis)
- 70.8 Obliteration of vaginal vault (without graft or prosthesis)

XX2 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect with Graft or Prosthesis without CC

- 70.5X Repair of Cystocele and Rectocele with graft or prosthesis
- 70.5X Repair of Cystocele with graft or prosthesis
- 70.6X Vaginal reconstruction with graft or prosthesis
- 70.7X Vaginal suspension and fixation with graft or prosthesis
- 70.8X Obliteration of vaginal vault with graft or prosthesis

YY2 Genitourinary Reconstructive Procedures for Repair of Pelvic Floor Defect with Graft or Prosthesis with CC

- 70.5X Repair of Cystocele and Rectocele with graft or prosthesis
- 70.5X Repair of Cystocele with graft or prosthesis
- 70.6X Vaginal reconstruction with graft or prosthesis
- 70.7X Vaginal suspension and fixation with graft or prosthesis
- 70.8X Obliteration of vaginal vault with graft or prosthesis

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Again, AMS thanks CMS for the opportunity to provide comments on the Proposed Rule on the Medicare Inpatient Prospective Payment System for FY 2007. If you have any questions regarding these comments, or if you would like additional information, please contact Gary Goetzke at 952-930-6155 or Jill Rathbun at 703-486-4200.

Sincerely,

John Nealon
Senior Vice President
Business Development

Gary Goetzke
Senior Director
Health Care Affairs

cc: Dr. Vincent Lucente, Chairman, PRC
Dr. Barbara Levy, Vice Chairman, PRC

RENAL LEADERSHIP COUNCIL

Providers of Quality Care for the Nation's Dialysis Patients

June 12, 2006

VIA HAND DELIVERY
Dr. Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **CMS-1488-P: Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule**

Dear Administrator McClellan:

The Renal Leadership Council (RLC) is pleased to have the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates (Proposed Rule).[1] RLC is a coalition representing eight dialysis organizations[2] that provide care to more than 70 percent of the dialysis patients in the United States. Collectively, RLC members operate more than 3,300 dialysis facilities in 48 states and the District of Columbia, providing care to more than 220,000 patients.

In brief, this letter focuses on CMS' request for comments about promoting the effective use of Health Information Technology (HIT), which is raised in the "Value-Based Purchasing" section of the Notice of Proposed Rulemaking.[3] RLC strongly agrees that HIT will facilitate better coordination of care and enhanced patient safety. As the Agency recognizes, accomplishing these goals requires the sharing of information not only within an organization, such as a hospital, but also with caregivers and providers outside of that setting. This view is consistent with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 2006 National Patient Safety Goals as well. The Frequently Asked Questions related to Goal 8 (Reconcile Medications) indicates:

> When discharging, referring, or otherwise handing over responsibility for the patient's care to another setting, service,

[1] 71 Fed. Reg. 23996 (2006).
[2] The RCL members include: American Renal Associates, Inc.; Centers for Dialysis Care; DaVita, Inc.; Fresenius Medicare Care North America; Northwest Kidney Centers; Renal Advantage, Inc.; Satellite Healthcare; and U.S. Renal Care, Inc.
[3] *See* 71 Fed. Reg. 24095, 24096, 24100.

> practitioner, or level of care within or outside the organization, it is expected that each organization has a process to communicate to the next provider or setting a list of all the medications that the patient is to be on following discharge or transfer...The discharge medication list must be communicated to the next provider of care in a time frame that is consistent with the anticipated follow-up activities.[4]

Sharing patient information among treating providers is of particular importance to patients with kidney failure, since these patients have, on average, two separate hospital admissions a year and a total of 15 days in the hospital. The weakest link in the coordination of care for patients with kidney failure is the lack of admission and discharge information available from a hospital to the patient's dialysis facility. This significant drawback in the system has an enormous impact on the provision of adequate patient care and survival, and hospital and dialysis facility function. Therefore, appropriate information exchange at both the beginning and the end of hospitalization is an essential component of providing adequate care to dialysis patients. The RLC encourages CMS to examine not only long-term solutions, but also short-term data sharing options that will allow patients to benefit immediately. CMS should require hospitals and dialysis facilities to exchange patient health care information to ensure the continuity of care for patients with kidney failure and to reduce inefficiencies in the provision of health care services.

Presently, there is no comprehensive, routine information transfer of information between hospitals and dialysis facilities. While the RLC supports continued exploration and utilization of HIT to improve the quality and delivery of health care services, CMS should provide an intermediate solution that will address the immediate barriers to the transfer of patient data between hospitals and dialysis facilities. Specifically:

- Consistent with both the requirements Hospital and End Stage Renal Disease Conditions of Coverage, there should be an automatic exchange of relevant patient information between a hospital and dialysis facility when a patient is admitted to the hospital;

- Hospitals should transfer appropriate patient data directly to the dialysis facility immediately prior to or at the time of the patient's discharge; and

- CMS should clarify that the Health Insurance Portability and Accountability Act (HIPAA) does not prevent the exchange of patient health information between a hospital and dialysis facility for treatment purposes.

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[4] *See* JCAHO, National Patient Safety Goals for 2006, at http://www.jointcommission.org/NR/rdonlyres/4CF20AC5-B125-4B22-9D0C-9C39B0EBD57B/0/06_npsg_faq8.pdf.

I. There should be an automatic exchange of information between a hospital and dialysis facility at the patient's admission to the hospital.

Because of the complicated nature of kidney failure, hospitalization is a common occurrence for the more than 400,000 Americans with this disease. Currently, hospitals are not required to share information about these patients, including patient admissions. Too often, the only way the facility discovers that a patient has been admitted is when he or she does not appear for dialysis. If the dialysis facility was informed of the patient's admission, it could not only provide the hospital with important patient health information, it could adjust its resources and staffing accordingly to prevent machines and dialyzers from being set up for patients who are already hospitalized and the underutilization of staff, both of which add unnecessary costs to the Medicare program and the healthcare system overall. Without such communication, hospital personnel often do not have access to a patient's current dialysis prescription, medications administered on dialysis, and summaries of other pertinent health problems, such as allergies.

This requirement would be consistent with the requirements of the ESRD Conditions of Coverage and Hospital Conditions of Coverage. The ESRD Conditions of Coverage state:

> The facility provides for the interchange of medical and other information as necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.[5]

Similarly, the Hospital Conditions of Coverage state that, "The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up ancillary care."[6] Therefore, we encourage CMS to mandate the automatic exchange of specific information about dialysis patients between hospitals and dialysis facilities.

RECOMMENDATIONS:

- Until an interoperative HIT system is in place, hospitals should be required to notify dialysis facilities via fax, phone, or email of a patient's admission.
- There should be a minimum exchange of information using a standardized format between the hospital and dialysis facility to ensure patient safety, continuity of patient care, and the efficient use of health care resources. Suggested information to be exchanged between a hospital and dialysis facility is set forth in Attachment A.

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[5] 42 C.F.R. § 405.2139(g).
[6] *Id.* at § 482.43(d).

II. Hospitals should transfer appropriate patient data directly to the patient's dialysis facility prior to or at the time of the patient's discharge from the hospital.

Similarly, a patient's dialysis facility often must resume the prior treatment course without knowing that a patient was hospitalized and what treatment occurred in that setting. The post-hospital course of treatment is determined by the appropriateness of discharge and adequate transfer of information back to the dialysis facility. Patients with kidney failure change both physiologically and biochemically during the course of hospitalization. For example, those with prolonged hospitalizations may either gain or lose fluid weight, lose lean body mass, develop more severe malnutrition or anemia, or experience other clinical situations which result in major changes in mineral and electrolyte content of their blood, and other laboratory values. Such changes often require major revisions in the dialysis prescription, such as fluid removal target, "dry weight" assessment, bath dialysate prescription, and injectable medication dosage, upon return from the hospital, which, if missed, could have grave consequences. Other important patient information is often infrequently transferred to dialysis facilities, such as oral medication changes and social services and dietary plans relating to immediate post hospital care. This lack of data exchange between the hospital and dialysis facility results in guesswork by the latter for much of the remaining post-hospital care.

To effectively coordinate patient care and protect patient safety, it is critical that patient information be transferred from the hospital directly to the dialysis facility at the time of the patient's discharge. Without the automatic transfer of information by qualified medical personnel, patient health is compromised and dialysis facilities are left in the precarious position of determining appropriate follow-up care without all of the available patient information. Therefore, we strongly encourage CMS to require hospitals to provide certain information about a patient's treatment to their dialysis facility upon discharge.

RECOMMENDATION:

- Until an interoperative HIT system is in place, hospitals should be required to notify dialysis facilities of the information listed in Attachment A using a standardized format via fax, phone or email within 24 hours of discharge.

III. HIPAA does not prevent the exchange of patient information between a hospital and a patient's dialysis facility for purposes of treatment.

When queried by dialysis facilities, many hospitals are hesitant to provide health information about a particular patient. Often these denials are based upon an erroneous understanding of the HIPAA Privacy Regulations. HIPAA specifically permits these types of disclosures because they are within the definition of "treatment."[7] This misinterpretation of

[7] 45 C.F.R. § 164.501.

HIPAA places the lives of thousands of dialysis patients at risks. Therefore, we strongly encourage CMS to clarify that hospitals may disclose a patient's protected health information to dialysis facilities for treatment purposes without first obtaining an authorization.[8]

RECOMMENDATION:

- CMS should clarify that HIPAA does not prohibit the use and disclosure of a patient's health care information between a hospital in which the patient has been admitted and the patient's dialysis facility for treatment purposes.

IV. Conclusion

The RLC members sincerely appreciate your review of our concerns related to the lack of routine transfer of information between hospitals and dialysis facilities. We thank you for the opportunity to comment and look forward to working with the Agency to resolve this issue. In the meantime, please do not hesitate to contact Kathy Lester at (202) 457-6562 if you have questions regarding these comments.

Sincerely,

Erin Darling
Acting Executive Director

[8] *Id.* at § 164.506 (Uses and disclosures to carry out treatment, payment, or health care operations); *see generally,* Health Insurance Reform: Security Standards, 45 C.F.R. Parts 160, 162, 164.

ATTACHMENT A

Hospital Admission

- The hospital should provide the following information to the dialysis facility:

  - Patient's admission date;
  - Service assignment;
  - Admission diagnosis;
  - Room number;
  - Attending physician;
  - Overall condition; and
  - Whether there is an immediate need for dialysis.

- The dialysis facility should provide the hospital with:

  - The patient's dialysis prescription;
  - Medication list, including injectables;
  - Estimated dry weight;
  - Injectables;
  - Patient allergies; and
  - Recommendations for continuing antibiotic treatments, if any.

Hospital Discharge

- The hospital should provide the dialysis facility with the following information at discharge:

  - Full dialysis prescription including dialysate composition, dry weight, heparin dose, and whether other new adjunct medication is required;
  - The patient's estimated dry weight and date of last hospital dialysis;
  - Overall plan for further follow-up, including dates and times for appointments established prior to discharge;
  - Need for any other adjunctive medication administration to continue in the outpatient setting (hyperalimentation, antibiotics, and duration of their treatment);
  - Changes in routine outpatient medication regimens;
  - Narrative summary of hospitalization (if available);
  - Death summary/autopsy report if the patient expires during hospitalization;
  - The patient's last set of electrolytes;
  - Procedures undertaken in the hospital;
  - Problem list on discharge relating to the hospitalization, including ICD 9 codes;
  - The results of x-rays and echocardiograms; and
  - Recommendation for further therapy, specifically antibiotics.

167

American
Clinical Laboratory
Association

June 12, 2006

VIA HAND DELIVERY

Dr. Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Comments on the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates – File Code CMS-1488-P

Dear Administrator McClellan:

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the proposed changes to the hospital inpatient prospective payment systems and fiscal year 2007 rates (the "Proposed Rule"). 71 Fed. Reg. 23996 (Apr. 25, 2006). ACLA is an association representing clinical laboratories throughout the United States, including local, regional and national laboratories. ACLA members perform a variety of clinical laboratory services for hospital patients, including anatomic pathology services. Both hospitals and clinical laboratories will be significantly affected by an impending change to the rules governing how anatomic pathology services are billed to the Medicare program when an independent clinical laboratory performs those services on behalf of a hospital. We urge CMS to begin educating hospitals about their new obligations under these rules, which are set to go into effect on January 1, 2007.

Summary

In 1999, the Centers for Medicare and Medicaid Services ("CMS") announced a change in the requirements applicable to billing for the technical component ("TC") of anatomic pathology services furnished to hospital inpatients and outpatients by independent laboratories. That change would have required laboratories to bill hospitals for the TC of those services. However, the Benefits Improvement and Protection Act ("BIPA") enacted a special grandfather provision that exempted certain hospitals from this provision. The provision was extended by the Medicare Modernization Act ("MMA"), but is now scheduled to expire at the end of 2006. As a result, beginning in 2007, independent laboratories will be required to bill hospitals for the TC of anatomic pathology services furnished to inpatients and outpatients. CMS must develop and implement a strategy for informing hospitals about these new requirements and encouraging them to begin taking steps to address these issues.

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Discussion

Until 1999, an independent laboratory was permitted to bill Medicare directly for the TC of anatomic pathology services furnished to hospital inpatients or outpatients. However, in the final physician fee schedule issued that year, CMS adopted a new policy that it would only pay the hospital for the TC of pathology services furnished to inpatients, even if the services were performed by independent laboratories. It was CMS' view that the DRG payment methodology compensated hospitals for the TC of physician pathology services. CMS subsequently issued a similar requirement for the TC of services furnished to outpatients, requiring the independent laboratory to bill the hospital for those services. *See* Trans. AB-00-73, Change Req. 1309 (Aug. 11, 2000).

However, the effective date of these requirements was subsequently delayed by Congressional action. Section 542 of BIPA states that a Medicare carrier can continue to pay an independent clinical laboratory for the TC of physician pathology services furnished to inpatient and outpatients so long as the hospital referring the services qualifies as a "covered hospital." For purposes of Section 542, a covered hospital is one that had an arrangement with an independent laboratory that was in effect as of July 22, 1999 (the date that CMS had first proposed the change in TC billing), under which the laboratory furnished the TC of physician pathology services to fee-for-service Medicare beneficiaries who were hospital inpatients and outpatients and submitted claims for payment for the TC to a carrier. The BIPA provision, which was supposed to expire on January 1, 2003, was subsequently extended by the MMA, until December 31, 2006. *See* MMA, §732.

As a result of the grandfather provision established under BIPA and extended by MMA, if a "covered hospital" refers physician pathology services to an independent laboratory, from a hospital inpatient or outpatient, then the laboratory can bill Medicare directly for the TC of those services, rather than bill the hospital. For hospitals that do not qualify as "covered hospitals," the laboratory is still required to bill the TC to the hospital. The Professional Component of the services could always be billed directly to Medicare.

Unless Congress takes action, the grandfather provision will expire at the end of the year. As a result, at that time, independent laboratories will be required to bill hospitals for the TC of physician pathology services ordered for inpatients and outpatients, and hospitals will be subject to hospital bundling rules. This means that for inpatients, the TC will be part of the DRG, and for outpatients, the TC will be paid under the APC payment. Accordingly, hospitals will have to establish new contractual relationships with clinical laboratories to provide these services to hospital inpatients and outpatients.

ACLA is very concerned about the impact of the expiration of the grandfather because it will require a significant change in the way that hospitals and clinical laboratories have historically done business. In addition, it is our experience that many hospitals are currently unaware of this impending change and therefore are not taking any steps to address these new

requirements. Given this major change to these historical billing rules, we strongly urge CMS to begin an immediate education campaign to help hospitals understand their new obligations and move forward to address them.

Thank you for the opportunity to present these comments. If you have any questions or would like additional information, please feel free to contact me.

Sincerely yours,

Alan Mertz / ED

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President

168

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VIA HAND DELIVERY

June 12, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
Room 445-G
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Washington, DC 20201

Attention: **CMS-1488--P**

Dear Administrator McClellan:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems [IPPS] and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006). The Association's Council of Teaching Hospitals and Health Systems (COTH) comprises nearly 300 general acute nonfederal major teaching hospitals and health systems that receive Medicare payments under the IPPS. The Association also represents all 125 accredited U.S. allopathic medical schools; 96 professional and academic societies; 90,000 full-time clinical faculty; and the nation's medical students and residents.

Our letter focuses primarily on two areas that have important implications for teaching hospitals and the academic medical community: a) proposed changes to the diagnosis-related group (DRG) weighting and classification systems, and b) a purported "clarification" that would prohibit hospitals from counting much of the time residents spend in didactic activities when calculating indirect medical education (IME) and direct graduate medical education (DGME) payments.

In brief, we do not oppose moving from a charge to a cost-based DRG weighting methodology, but believe that a one-year postponement is necessary to allow for further analyses to address data and computation issues and to ensure that the best possible methodology ultimately is implemented. We also support refinement of the DRGs but believe that the proposed consolidated severity-adjusted DRGs (CS-DRGs) require

further examination and likely modifications before implementation. We believe these changes should be implemented simultaneously to ensure equity and minimize payment volatility for hospitals. Finally, because they could result in the redistribution of over a billion dollars in Medicare payments among hospitals, a significant transition period should accompany the changes.

Concerning the DGME and IME issues, we strongly urge CMS to rescind the purported "clarification" in the proposed rule. The Agency should instead reaffirm its 1999 position defining patient care activities to include didactic activities.

In this letter, we also comment on several other important issues raised in the proposed rule, including: the outlier threshold, reporting hospital quality data, and payment for new technologies. We also include our perspectives on value-based purchasing, hospital-acquired infections, and the Department of Health and Human Services ("Department") health care information transparency initiative.

ROLE OF MEDICARE AND TEACHING HOSPITALS

The Medicare program and teaching hospitals share a long and mutually beneficial history. Since 1965, Medicare has recognized and provided financial support to teaching hospitals for their unique roles extending beyond the traditional patient care service mission. These include being sites for the clinical education of all types of health professional trainees; providing environments in which clinical research can flourish; being sources of specialized, unique, and referral/standby services; and serving as safety net providers for the poor and uninsured. Because of their education and research missions, teaching hospitals offer the newest and most advanced services and equipment, and often care for the nation's sickest and most complex patients.

Medicare helps offset the costs of educating medical residents through DGME payments. Medicare IME and disproportionate share (DSH) payment adjustments in the inpatient PPS reflect recognition of the higher patient care costs and other socially valuable activities of teaching hospitals. Outlier payments offset a portion of the large losses that teaching hospitals incur when they treat extraordinarily high cost Medicare patients. Combined with DRG payments, these Medicare operating payments are critical for teaching hospitals to maintain their important missions which benefit Medicare and all patients.

However, when one looks at recent trends in Medicare payments and policies, there is serious cause for concern. According to CMS estimates, in the last 10 years, increases in Medicare average operating payments per case for major teaching hospitals have lagged significantly behind other hospital groups and even the IPPS update.[1] Since FY 1998, Medicare IME support has fallen by nearly 30 percent, and will be reduced again on

[1] Since 1996, the cumulative change in average Medicare operating average payment per case for major teaching hospitals was 19 percent, compared to 33 percent for all hospitals and 26 percent for the IPPS update. Source: IPPS Operating Payment Impact Files.

October 1. The number of residents that Medicare will support is now capped at 1996 levels. Questionable and narrow interpretations of DGME and IME policies, such as those included in this proposed rule, and others,[2] have resulted in teaching hospitals and their academic leaders often being forced to choose between retaining critical DGME and IME support dollars and ensuring that residents spend time in ambulatory training sites, are exposed to clinical research activities, and keep up with the latest developments in scientific and quality initiatives.

We are beginning to see erosion in the missions of some teaching hospitals. It is critical that before further damage is done Medicare policymakers and academic leaders work together to ensure, as was promised in 1965, that Medicare continues its support of the vital missions of teaching hospitals that represent the cornerstone of America's health care delivery system.

PROPOSED CHANGES TO THE DRG WEIGHTING AND CLASSIFICATION METHODOLOGIES

Because it has approximately 42 million beneficiaries, the vast majority of whom are over 65, the importance of the Medicare program to hospitals and the health care system generally is self-evident. Consequently, significant changes to the program, such as those proposed, have a profound effect. Moreover, one must also keep in mind that many Medicaid and private sector payers follow Medicare's payment methodology. This ripple effect reinforces the imperative that significant changes to the Medicare system, like the DRG weighting and classification changes, must be subjected to comprehensive and thorough analysis to ensure that the goals of the intended policy change are met without undue stress to the system.

Current System

Under the IPPS, Medicare pays hospitals a per case payment that varies according to which diagnosis-related group (DRG) the case is assigned and the DRG's payment "weight."[3] Each weight is intended to represent the average hospital resources required to treat a case within a DRG compared to the average required per case resources across all DRGs. Thus, cases that require higher levels of resources, on average, will have higher weights than cases that require relatively lower levels of average resources.

Cases are assigned to one of 526 DRGs, predominantly based on the patient's principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay. The determination of which case types comprise a DRG is based on both clinical coherence and similar resource consumption. Hospitals do not decide to which

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[2] Another example is the Agency's interpretation of "all or substantially all" training costs in nonhospital settings.

[3] These payments may then be adjusted for other purposes, such as whether the hospital is located in a high or low wage area, whether it is a teaching hospital, and whether it treats a disproportionate share of low income patients.

DRG a case is assigned. Rather the assignment is done by the Medicare GROUPER software program, based on the diagnosis and procedure code information provided by the hospital.

Currently, the DRG weights are based on Medicare-allowable charges per discharge. These charges are standardized to remove the effects of differences in area wage levels, IME and DSH payments and, for hospitals in Alaska and Hawaii, the applicable cost-of living adjustment.

An average standardized charge per DRG is then calculated by summing the standardized charges for all cases in the DRG (excluding those cases whose charges are viewed as unreasonable based on statistical tests) and dividing by the number of transfer-adjusted cases in the DRG. Each DRG's average standardized charge per case is then divided by the national average standardized charge per case to determine its relative weight.

Proposed Changes

Under the proposed rule, in FY 2007 Medicare would move to a "hospital-specific relative value cost center" (HSRVcc) DRG weighting methodology. In FY 2008 ("if not earlier" according to the proposed rule) the current 526 DRGs would be replaced by 861 "consolidated severity-adjusted DRGs" (CS-DRGs). According to the proposed rule press release, these two proposals represent the "first significant revision of the Inpatient Prospective Payment System (IPPS) since its implementation in 1983."

Proposed HSRVcc DRG Weighting Methodology[4]

The HSRVcc methodology is an alternative to a weighting methodology that has been recommended by the Medicare Payment Assessment Commission (MedPAC) (See *March 2005 Report to the Congress: Physician-Owned Specialty Hospitals*). It involves two basic steps. The concept underlying the first step is to create "relative values" for each hospital. This is attempted by dividing the hospital's average charge per case for each of 10 cost centers[5] for each DRG by the average charge for that cost center for all of the hospital's cases. The result is 10 relative weights for each DRG for each hospital. These weights are then aggregated to the national level so that there are 10 cost center relative charge weights for each DRG.

The second step involves blending the 10 relative weights for each DRG through a "scaling" process in which the contribution of each of the 10 cost center relative weights to the final, single DRG weight depends upon that cost center's estimated national costs relative to total costs (the sum of all of the cost centers). The estimated costs are derived by multiplying national average cost-to-charge ratios (CCRs) by national total charges for

[4] Note that this description is conceptual in nature. We have identified a number of flaws associated with the methodology that are not reflected in this discussion.
[5] Routine days, intensive days, drugs, supplies and equipment, therapeutic services, operating room, cardiology, laboratory, radiology, and other services and charges.

each cost center. The resulting estimated costs for each cost center are then summed to obtain an overall cost number. "Scaling" factors are then obtained by taking the estimated costs for each cost center and dividing by national total estimated costs.

Consolidated Severity-Adjusted DRGs (CS-DRGs)

The 861 CS-DRGs represent a consolidated list of the 1,258 "All Patient Refined" DRGs (APR DRGs) designed by 3M Health Information Systems. The major feature that distinguishes APR-DRGs is four severity illness subclasses (minor, moderate, major and extreme) for each base DRG. The determination of the severity subclass is based on an 18 step process that takes into account secondary diagnoses, principal diagnosis, age and procedures. The APR DRG structure does not currently accommodate case distinctions based on complexity, such as the use of devices, drugs, and equipment which could significantly increase treatment costs (71 Fed. Reg. at 24014).

The consolidation of the APR DRGs to the CS-DRGs is largely the result of combining severity subclass four across the entirety of APR DRGs into fewer groups (from 262 to 69). Compared to the current DRGs, the net result of CS-DRGs is a substantial re-arrangement of the current base DRGs and the addition of severity classes.

Analyzing the Proposed Changes

Despite the obvious complexity associated with the methodology, combined with the major financial impacts associated with the resultant DRG weight changes, hospitals were given only 60 days to review and comment on the proposed rule changes. During this period, the AAMC and its member teaching hospitals have conducted numerous analyses to try to understand the policy goal of the proposals, the underlying methodologies, and the resulting impacts. The AAMC, along with the American Hospital Association (AHA) and Federation of American Hospitals (FAHS) contracted with The Moran Company to recreate the CMS database and methodology. Accomplishing this was no easy task. We wish to express our appreciation to CMS for holding a special teleconference to address technical questions associated with the proposal and to CMS staff who patiently responded to data requests and technical questions during the comment period. Specific comments about each of the proposed changes are discussed below.

Overall Impact of the Proposed Changes

While in aggregate the proposed rule changes are budget-neutral, if implemented over a billion dollars in Medicare payments would be significantly redistributed among hospitals as well as among DRGs. Of the 20 hospitals facing the greatest payment reductions in

2007 under the HSRVcc system, 19 are teaching institutions.[6] As a group, the 266 members of the AAMC's Council of Teaching Hospitals and Health Systems (COTH) that are subject to the IPPS, would face an estimated net payment reduction of 1.7 percent, or approximately $413 million dollars. While 36 percent of COTH members would see average Medicare payment increases of one million dollars, the average reduction for the remaining COTH members is three million dollars.

Adding CS-DRGs would ameliorate the payment reductions for COTH members as a group, from -1.7 percent to -0.8 percent, but 23 percent of COTH members would see reductions under both the HSRVcc and CS-DRG changes.

At the DRG level, the proposed rule notes that a number of DRGs would experience payment reductions, particularly DRGs involving cardiac care. For example, cardiac procedures involving stents, both drug eluting and non drug eluting, would see significant payment reductions. We are concerned about such drastic reductions for these and other cardiac procedures. While, the payment reductions could "potentially reduce the incentives . . . for the further development of specialty hospitals" (71 Fed. Reg. at 24006), we are concerned that the reductions also would significantly affect community and teaching hospitals that provide substantial amounts of cardiac care. Unlike many specialty hospitals, these hospitals have emergency rooms, treat significant numbers of Medicaid and uninsured patients, and also accept complex cardiac cases.

At the same time, we recognize and appreciate that a number of more "routine" DRGs, such as pneumonia, would see payment increases. These cases often result from emergency room admissions, which disproportionately occur in teaching and other safety net hospitals.

The AAMC's Overarching Views of the Proposed Changes

The AAMC recognizes the authority and need for CMS to make appropriate changes to the Medicare IPPS payment methodology to improve the accuracy, validity, and reliability of the system. We are concerned, however, that these overall objectives could inadvertently be subordinated to a desire to address a specific issue such as physician-owned specialty hospitals, particularly cardiac specialty hospitals. We appreciate CMS's recognition that these hospitals pose a significant threat to the stability of the health care marketplace. We urge CMS to continue the suspension of issuing new provider numbers to physician-owned limited service programs until the Agency's strategic plan, mandated by the Deficit Reduction Act of 2005, has been implemented and Congress has reviewed CMS's final report.

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[6] Note that all of the estimates contained in this comment letter reflect the correction to the transplant DRG weights. CMS inadvertently calculated and published DRG weights for these DRGs using data that included organ acquisition costs. Because these costs are reimbursed outside of the DRG system, they should not be included in the weight calculations.

To the extent that changes are offered that are intended to improve the payment system, they must be carefully analyzed and assessed. Because such budget-neutral changes naturally result in payment "winners" and losers" it is critical that the underlying policy rationale for the change be sound and, if that test is met, implementation of that change be accomplished with a methodology that best achieves the policy goal. Finally, because Medicare is a critical revenue source for hospitals, to the extent the changes result in significant payment reductions, these reductions must be phased in over a reasonable period so that hospitals have time to transition to the new system without experiencing significant disruptions to operations.

1. The AAMC is not opposed to moving to a DRG weighting methodology based on the costs of providing care so long as it improves the accuracy of the payment system and the methodology is sound, stable, and reliable.

We support the idea of moving to cost-based weights, despite the fact that a number of major teaching hospitals would likely see payment reductions. However, a change of this magnitude cannot be entered into precipitously.

While seemingly a simple concept, developing "cost based" weights is actually a complex undertaking. Calculating the costs for a particular Medicare case cannot be accomplished directly. Consequently these costs must be "estimated" using cost-to-charge ratios (CCRs) that are reported on hospitals' Medicare cost reports and applying them to charge amounts that are reported on Medicare claims. However, even then, there are various ways of utilizing the CCRs and implementing a cost-based methodology. The methodology developed by the Medicare Payment Advisory Commission (MedPAC) is significantly different than the HSRVcc methodology. In addition there are modifications to both of these methodologies that also should be considered.

We believe more work is needed to determine the best way to develop cost-based weights. We are committed to working with CMS and other hospital organizations to identify an appropriate methodology.

2. The AAMC is in favor of refining the DRGs to better reflect patient severity and complexity, but we have serious concerns whether the proposed CS-DRGs achieve this goal. Further study, and likely changes, to CMS's proposed CS-DRGS are needed.

We appreciate CMS's recognition of the need to better account for patient severity in the IPPS. It is important that the DRG classification system accurately reflect those cases that involve the sickest and most complex Medicare patients. As common sites of care for these patients, ensuring that these cases are assigned to DRGs that adequately reflect the resources needed is a fundamental principle for major teaching hospitals.

We have concerns, however, about the proposed CS-DRGs, in part because they reflect patient severity only and do not recognize service complexity. CMS agrees with these

concerns, stating that "a method of recognizing technologies that represent increased complexity . . . should be included in the system." (71 Fed. Reg. at 24014). We are very interested in the proposed rule statement that CMS plans to "develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments." (Ibid). How CMS determines these criteria and their resultant impact on the classification system will have important implications for the IPPS.

3. Implementation of a "cost-based" DRG weighting methodology should be postponed for one year to allow for further work. This change should then be implemented simultaneously with an appropriate expansion of the current DRGs.

As discussed above, and below, additional analysis is needed before a significant change to the DRG weights can be implemented. Consequently, we believe that the implementation of any such changes should not occur on October 1, 2006 but rather should be postponed for one year. A one year delay would also allow for the simultaneous implementation of the new weighting methodology with refined DRGs. Each of these changes significantly redistributes payments, often in off-setting ways. Implementing both together would minimize the volatility associated with two separate changes.

4. A significant transition period must accompany these changes.

We appreciate the proposed rule's request for comments regarding a transition period (71 Fed. Reg. 24028).

Historically, Medicare changes of significant magnitude have included some type of transition period. For example, the move to a PPS for capital was transitioned in over a 10 year period. Other changes that were accompanied by transitions include: implementation of the operating IPPS (four years), eliminating day outliers (four years), and removing the costs of teaching physicians and residents in the calculation of the wage index (four years).

While it is unclear what an appropriately devised new DRG classification and weighting system might look like, it is obvious that such a change will still involve the redistribution of hundreds of millions of dollars. Accordingly a significant transition period must accompany any final changes.

Payment Accuracy

We appreciate CMS's efforts to find an "administratively feasible approach to improving the accuracy of the DRG weights." (71 Fed. Reg. at 24006). However, we have serious concerns whether the proposed approach achieves that goal and we also are concerned

that the desire to achieve ease of administration might result in a methodology that does not appropriately improve the payment system.

In the press release accompanying the proposed rule, the CMS Administrator stated that the proposed changes would mean that "payments for hospital inpatient services will more accurately reflect the costs of providing the services." Thus, we were particularly disappointed to find that the proposed rule did not contain statistical evidence that the HSRVcc system alone, or in combination with the CS-DRGs, improves payment accuracy. Instead, CMS relies on the payment accuracy analysis of the MedPAC methodology to support its position (71 Fed. Reg. at 24006, FN 1). However, MedPAC's methodology differs significantly from what CMS proposes.

Assessment of "payment accuracy" conducted by The Moran Company as well as The Health Economics and Outcomes Research Institute (THEORI), a division of the Greater New York Hospital Association (GNYHA), finds the CMS HSRVcc approach to be at best marginally better than the current system. Fixing the major methodological flaws yields minimal improvement, according to THEORI. CMS's HSRVcc approach actually creates new areas of care where systematic incentives for specialization could occur. Moreover, the CS-DRGs as designed by CMS appear to worsen, rather than improve, payment accuracy. We encourage CMS to carefully review GNYHA's comment letter which contains detailed information about THEORI's modeling and analyses.

These findings raise significant questions about CMS' approach and further analysis should be conducted before any changes to the current charge-based methodology are made. We believe, however, that the analyses conducted by The Moran Company, THEORI, and other data analysts will provide important information as the hospital community and CMS seek to find the most effective and administratively feasible approach for a shift to cost-based weights in FY 2008.

Specific Comments on the HSRVcc Methodology

As we indicated, the proposed HSRVcc methodology is complex, and involves working with extraordinarily large amounts of data, including thousands of hospital cost reports and the entire Medicare claims data set. CMS staff also had to deal with detailed cost and charge information at the individual cost center level.

We appreciate the work done by CMS staff in their efforts to not only develop the proposed methodology but also to do analyses demonstrating the impact of the proposals, both at the DRG and hospital levels. We make the following specific comments and observations to demonstrate that more time is needed to better study the CMS proposal and possible modifications, as well as assess alternatives that might better achieve the goal of payment accuracy.

In the limited 60 day period that we have had to analyze these significant and complex proposed changes, we have identified a number of methodological issues relative to how

CMS calculated the HSRVcc weights. For example, contrary to the statement in the proposed rule, CMS inadvertently included organ acquisition costs in the data used to set the weights for transplant DRGs. Correction of this error significantly reduces the weights that were published in the proposed rule. As a result, rather than seeing payment increases, as reflected in the proposed rule DRG weights, payments for most transplant DRGs would actually significantly decrease under the proposed methodology. For example, the current weight for DRG 495 (lung transplant) is 8.5736. The weight published in the proposed rule, reflecting the HSRVcc methodology, is 10.0603. When corrected by The Moran Company, the weight is 7.3354.

We also believe CMS may have erred, or at least made serious questionable methodological decisions on a number of other issues, including the "weighting" methodology used in the calculation process (i.e., calculating national cost-to-charge ratios (CCRs) through an averaging process that treats each hospital's CCR equally and does not account for differences in case volume). Another is how data used to develop the DRG weights were "trimmed" (i.e., excluding a significant number of hospitals in the data calculations because CMS staff felt the data were "aberrant"). These decisions, particularly the CCR weighting decision, significantly impact the DRG weights.

More minor inconsistencies that were discovered by The Moran Group included:

- Including Maryland hospitals in the HSRVcc calculations, but not in the CS-DRG calculations,
- Ambiguity regarding the use of transfer-adjusted versus non transfer-adjusted case counts and charges, and
- Inconsistent data "cleaning" policies.

In addition to the data and methodological implementation issues, we believe more time is needed to review and understand the data that would be used in the weight calculations and other determinations made by CMS. For example, the selection of the cost centers used in the proposed methodology is a key decision that has important implications for the final DRG weight determinations. Yet, CMS provided very little information to explain its selection of the 10 cost centers except to say that they were based upon "broad hospital accounting definitions" and that each center represents at least five percent of the charges in the claims data.

Integral to the selection of the cost centers is the related issue of the costs and charges associated with those cost centers. Because hospitals often report charges on the cost reports differently than charges on the claims, the cost-center level CCRs are calculated based on a different set of charges than the charges to which the CCRs are later applied. We believe this may materially distort the DRG weights and needs to be thoughtfully considered and accounted for in any methodology.

We also believe that more discussion and thought must be devoted to the appropriate "standardization" process regardless of whether it is applied to costs or charges. The

current system standardizes for wage index, and IME and DSH payments. By contrast, the proposed methodology uses a "hospital-specific relative value" that was also used by MedPAC. We believe a more thorough analysis is needed to understand the differences between the two methods to determine which one is more appropriate.

Specific Issues with the CS-DRGs

We strongly agree with the statement in the proposed rule that "there are still further changes that we believe may be important to make to [the CS-DRG] system before it is ready for adoption." (71 Fed. Reg. 24011). As discussed above, it does not appear that as currently constructed the CS-DRGs improve payment accuracy.

It has been very difficult for us and our member hospitals to fully analyze the CS-DRG methodology because CMS did not publish a CS-DRG grouper. Instead, CMS provided a link to the 3M web site that implies that hospitals could conduct their own analyses of the impact of moving to CS-DRGs. However, the reality is that if a hospital does not have its own APR-DRG grouper software, it can only obtain CS-DRG information on a case-by-case basis, for which hospitals have to enter all diagnostic and procedure codes for each case.

The only other alternative was for hospitals to purchase the 2004 MedPAR which contains the current DRG assignment and the proposed CS-DRG assignment for all Medicare cases for all hospitals in the country. But again, this information was only available for 2004 and it does not allow for hospitals to probe the logic for how the assignments were made. The current DRG grouper logic has been in the public domain since the inception of the IPPS. Likewise, we believe that any changes to the grouper logic also must be in the public domain.

The proposed rule acknowledges that technologies that represent increased complexity but not necessarily greater severity of illness are not explicitly recognized in the APR DRG system (71 Fed. Reg. 24014). Ensuring that both severity and complexity are accounted for is imperative in any new classification system.

We also believe strongly that if CMS makes changes to the DRG classification system, the DRG assignment methodology and accompanying GROUPER software must recognize additional diagnosis and procedure codes, beyond the current nine diagnoses and six procedures. Analyses conducted by the University HealthSystem Consortium indicate that using more codes would result in claims receiving a more accurate DRG assignment. Hospitals submit claims to CMS in an electronic format. The HIPAA compliant electronic transaction 837i standard allows up to 25 diagnoses and 25 procedures. Additional codes will allow for more precision in identifying patient severity and resource use so that cases are assigned to the most appropriate DRG.

Finally, as CMS does further analyses on refining the DRGs, we encourage staff to pay particular attention to any changes to cases that currently are assigned to DRGs 541 or

542--ECMO or tracheostomy with mechanical ventilation 96 hours plus, with (DRG 541) or without (DRG 542) major OR procedure. These patients, who are disproportionately treated in teaching hospitals, are very complex, requiring extraordinary hospital resources. This is reflected in the current weights for DRGs 541 and 542 of 19.8038 and 12.8791, respectively. Analyses done by several of our member hospitals (that have APR-DRG software) show that under CS-DRGs, some of these cases would be assigned to CS-DRGs with significantly lower weights—as low as one. We believe that given the complexity and fragility of these patients, any changes to their DRG assignments merit special scrutiny.

COUNTING RESIDENT TIME FOR DGME AND IME PAYMENT PURPOSES

We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes most medical resident time spent in didactic activities in the calculation of DGME and IME payments (71 Fed. Reg. at 24114-115).

The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care." The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

We are dismayed that this issue is being raised now, but at the same time welcome the opportunity to allay any CMS concerns that these activities are not part of the patient care education of residents. Medicare has a long history of support for residency training programs, programs that have always consisted of many elements, including so-called "didactic" training, each of which is necessary to produce a physician. Simply put, with the acknowledged exception of extended periods of time spent doing "bench research" there is no residency educational or training experience that is not related to patient care activities.

The learning model used in graduate medical education is the delivery of care to patients under supervision of a fully-trained teaching physician. Everything residents learn as part of approved residency training programs is built upon the delivery of patient care and the residents' educational development into independent practicing physicians. To conclude otherwise would be wrong. This is even more true today than it was in the past, as it is now widely recognized that providing quality patient care requires physicians to have "medical knowledge about established and evolving biomedical, clinical and cognate (e.g., epidemiological and social-behavioral) sciences and the application of this knowledge to patient care" (ACGME Institutional Requirements, III(E)(1)(b)).

We urge CMS in the final rule to reconfirm the Agency's 1999 position that recognizes didactic activities as an integral component of the patient care activities engaged in by

residents during their residency programs and to allow this time to be counted for purposes of IME and DGME payments, both in hospital and nonhospital settings.

Background

The amount of Medicare DGME and IME payments that a teaching hospital receives is, in part, a function of its allowable "full time equivalent" (FTE) count of residents that are in accredited residency programs. According to the Medicare regulations, time that is eligible to be counted in the calculation of the FTE count includes time spent training in all areas of the hospital complex, as well as nonhospital sites if the hospital incurs "all or substantially all" of the training costs at that site (see 42 CFR 413.75 et. seq. (DGME regulations) and 42 CFR 412.105 (IME regulations).[7] The regulations do not define how many hours of training comprise one FTE. The IME regulations state that " full time equivalent status is based on the total time necessary to fill a residency slot" (42 C.F.R. 105(f) (iii)(A)). The DGME regulations have a similar definition (see 42 CFR 413.78(b)).

Hospitals have been allowed to count resident time spent in nonhospital sites for purposes of DGME payments since July 1, 1987 as authorized by the Comprehensive Omnibus Budget Reconciliation Act (COBRA) of 1986. The specific statutory provision states that "only time spent in *activities relating to patient care* shall be counted . . ." (emphasis added) (Section 1886(h)(4)(E) of the Social Security Act (SSA)). Resident time spent in nonhospital sites could not be counted for IME purposes until 1998, when it was authorized by the Balanced Budget Act of 1997 (BBA). The IME nonhospital site statutory provision states that "all the time spent by an intern or resident *in patient care activities* shall be counted towards the determination of full-time equivalency. . . (emphasis added) (Section 1886(d)(5)(B)(iv)).

The statutes authorizing DGME and IME payments in the hospital complex contain no requirement that residents be engaged in "patient care activities" in order to include the time in the calculation of the resident FTE count.

Proposed Rule

To support its position, CMS focuses the discussion on the meaning of the phrase "patient care activities" in the respective DGME and IME nonhospital site statutes. In an attempt to "clarify" the Agency's policy regarding how much of the time residents spend in ambulatory settings can be included in hospitals' FTE counts, and "resolve any confusion," the proposed rule announces definitively that when they occur in nonhospital settings, didactic activities "cannot be included in a hospital's direct GME or IME FTE resident count." (71 Fed. Reg. at 24115). According to the preamble, these activities

[7] For the IME calculation, time spent in those areas subject to the IPPS are counted for purposes of the inpatient IME adjustment. Resident time spent in IPPS-excluded psychiatric and rehabilitation units are used in the calculation of the IME adjustments associated with the inpatient psychiatric facility (IPF) and inpatient rehabilitation (IRF) prospective payment systems.

include journal clubs, educational conferences, classroom lectures, and seminars.[8]

CMS acknowledges that "patient care activities" (71 Fed. Reg. at 24115) have never been defined explicitly in regulation. From the preamble discussion, readers learn that CMS staff believe they must apply the "plain meaning" of the phrase, which CMS chooses to define as the "care and treatment of particular patients, or to services for which a physician or other practitioner may bill" and "would certainly not encompass didactic activities." (71 Fed. Reg. at 24115). This pronouncement contradicts a 1999 letter from a senior CMS official stating that CMS interprets "'patient care activities' broadly to include any patient care oriented activities." (September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care, HCFA to Scott McBride, Esq., Vinson and Elkins) (See Attachment A).

The letter from Division Director Hefter goes on to say that these activities include "scholarly activities, such as educational seminars, classroom lectures, research conferences, patient care related research as part of the residency program, and presentations of papers and research results to fellow residents, medical students, and faculty." (Ibid). Offering no explanation to support what appears to be a change in position, CMS now merely states that the 1999 letter was "inaccurate" without any accompanying reasoning.

Because the statutory language that authorizes DGME payments for residents training within the hospital complex contains no direct reference to "patient care activities," the proposed rule confirms that <u>all</u> resident time that is part of an approved program may be included in hospital's FTE resident count. Likewise, for IME there is no direct reference to "patient care activities" in the statutory language authorizing IME payments associated with residents training within the hospital complex. Consequently, in the proposed rule, CMS relies solely on the general Medicare "reasonable costs" regulations (42 C.F.R. 413.9) to support its position.

It is worth noting that CMS states that its IME patient care requirement is a "longstanding policy" and reproduces a statement from the August 1, 2001 inpatient final rule (66 Fed. Reg. at 39897) which states that "we do not include residents in the IME count to the extent that the residents are not involved in furnishing patient care . . ." However, CMS failed to include the remainder of the text which states "but are instead engaged exclusively in research." These excluded words put in context what CMS was trying to convey in that rule--that in terms of research activities, only those that are patient-related may be counted. Nowhere is the word "didactic" ever mentioned.

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[8] While not the topic of this comment letter, it is worth noting the contradiction between CMS's position here and the Agency's position regarding the nonhospital site "all or substantially all" requirement. In order to meet the statutory requirement that hospitals pay "all or substantially all" of the nonhospital site training costs, CMS has asserted that hospitals must pay the supervisory physician costs, but only for the time associated with didactic and other activities. The result is that CMS seems to want hospitals to pay supervisory physicians' costs for resident time in didactic activities, yet does not want the hospital to be allowed to claim that time for DGME or IME payments.

The Nonhospital IME and DGME Statutes Support the Counting of Didactic Activities

CMS has cited no legislative history that clearly illuminates the reasons for the patient care references in the nonhospital site provisions. However, we have long believed that the references were intended to generally focus on patient care *settings,* such as physician offices and other ambulatory care sites. As a result of this interpretation, hospitals do not include in their FTE counts extended periods of time in which residents are engaged exclusively in basic science "bench" research outside of the hospital. The statutory language is also cited as the reason hospitals do not claim the time that preventive medicine residents spend in state and local public health departments because these sites do not involve "patient care."

We believe there are ample indirect legislative references to allow CMS to reconfirm in the final rule its position as set forth in the 1999 letter. First, multiple examples of legislation and accompanying report language demonstrate Congress' commitment to encouraging increased residency training in nonhospital sites, including:

- Explicit legislative actions in both COBRA 1986 and BBA 1997 to make clear that Medicare would provide for DGME and IME payments in ambulatory settings,

- A statement in the conference report accompanying the BBA 1997 IME nonhospital site provision expresses concern about "the lack of data on the number of residents receiving training in ambulatory care sites" and directs the Secretary to develop an inventory of sites and resident counts, and

- A BBA 1997 provision to allow for Medicare DGME payments to qualifying nonhospital providers.

It seems clear that Congress wants Medicare policy to encourage, not limit, residency training in ambulatory sites.

Second, as CMS (then HCFA) said in the 1999 letter, the statutory language itself reinforces the position that activities relating to patient care may be interpreted more broadly. The phrase "relating to" and the word "activities" certainly convey a broader meaning than that put forth in the proposed rule. It would certainly seem that if Congress wanted to narrow the breadth of Medicare-supported resident activity in the way as now suggested by CMS, the statutes would explicitly state that only time spent "delivering patient care" could be counted. That Congress did not, in fact, use this common language is convincing evidence that something broader was meant than the proposed rule position. This interpretation is further bolstered by the fact that since 1986 and 1998, didactic activities have been counted for IME and DGME payment calculations,

respectively, without objection, to the best of our knowledge, by any member of Congress.

To provide an independent legal perspective on this issue, we asked Tom Coons, a partner with the law firm Ober/Kaler, and a former supervisory litigation attorney with the Health Care Financing Administration (HCFA), to offer his opinion on the discussion in the proposed rule. Mr. Coon's unequivocal opinion is that the inclusion of resident didactic time in the calculation of the hospital's resident FTE count is legally permissible for both IME and DGME, in both hospital and nonhospital settings. (See Attachment B).

Didactic Activities are an Integral Component of Residents' Patient Care Activities

Whether it be grand rounds presentations, morbidity or mortality conferences, journal clubs or other so-called didactic activities that residents engage in during their residency programs, all of these activities are an integral part of patient care. Much of the learning is case-based, centered on a patient dilemma or case history. Residents frequently discuss patients for whom they are currently caring in these settings, as that makes the learning more relevant and helps them care for their patients.

Further support that there is no distinction between patient care and other activities that occur during the residency period can be found by comparing undergraduate medical education with GME. Within medical school, the educational experience is intended as a curriculum of learning in a variety of core subject areas (for example, anatomy and physiology). The focus is not as much on patient care delivery per se as it is on learning the basic tenets of medicine. Physician residents, as students, continue to learn but do so within the context of the delivery of patient care. The bottom line is that the basic science lectures are the domain of undergraduate medical school curriculum. Patient care learning is the domain of the residency program.

There may be relatively uncommon situations when a resident spends an extended block of time (for example a month) engaged in a purely educational or bench research activity and during which time the resident is not on call to a medical facility and has no patient care responsibilities. It might be reasonable to exclude the time spent in these activities from the FTE count. However, because these situations are far from the norm, they should not serve as the rationale for excluding all didactic activities. Most didactic activities are of relatively short duration, occurring in hour long or sometimes half day or full day increments. During these periods, residents often continue to have direct patient care responsibilities, as evidenced by frequent nurse pages, blackberries buzzing, and absences as residents respond to emergencies. From an educational perspective, this is not an ideal situation, but it is the reality for most residents.

Finally, it is important to remember when thinking about this issue that residents routinely train more than 40 hours a week, and often average up to 80 hours a week. If CMS were to count a resident FTE in the traditional manner of 40 hours a week (as the

Agency does for purposes of calculating the hospital wage index) didactic activities, even under the most stringent interpretation, would not affect the overall FTE count.

All Resident Training Time in the Hospital Complex Should Be Counted for IME Payment Calculations

As Mr. Coon's legal memorandum convincingly demonstrates, regardless of the interpretation, all resident time in activities that occur within the hospital complex must be included in the IME resident FTE count. We wholeheartedly agree with CMS that all of this time is countable for the DGME resident FTE count because the inpatient DGME statute includes no reference to patient care. Likewise, the IME inpatient statute contains no patient care requirement. Therefore all of the residents' time spent in approved activities in the hospital complex must be allowable for IME payment purposes.

Given Mr. Coons' opinion, we believe that imposing any other interpretation would be totally unwarranted from a legal perspective. Because the IME statute is clear on this point, CMS has no need to even look to the unrelated "reasonable cost" regulations to determine whether this time is countable.

A Misguided Interpretation of "Patient Care Activities" Would Result In Oppressive and Impractical Documentation Burdens

If a misguided interpretation of "patient care activities" were to be implemented, not only would it be wrong at the policy and legal levels, it also would increase, unnecessarily and enormously, teaching hospitals' documentation burdens.

As highlighted in another section of this year's proposed rule entitled "Counting and Appropriate Documentation of FTE Residents" (see discussion below), teaching hospitals already are subjected to substantial and burdensome documentation requirements to substantiate the resident FTE counts they report for DGME and IME payments. Based on language in this section of the proposed rule, we are very concerned that CMS could require hospitals to document residents' activities in hour-long increments so that they could identify didactic activities.[9] This would be a sea change for many teaching hospitals because resident training assignments are most often assigned in monthly or weekly rotation blocks. For some programs, half day schedules could be the norm. Training opportunities such as conferences and journal clubs often are not included on the rotation schedules. For teaching hospitals that have hundreds and possibly thousands of residents to track, creating and maintaining documentation in hour long increments is

[9] The text of the proposed rule discussion states "it is important for hospitals to be able to document the activities in which residents are engaged because there are certain activities that are not allowable for direct GME or IME payment purposes . . ." (71 Fed. Reg. at 24114).

literally not achievable.[10] Residents are not workers who must record every activity, but students being exposed to a wide range of experiences, all of which further their education and benefit their current and future patients.

REQUIREMENTS FOR COUNTING AND APPROPRIATE DOCUMENTATION OF FTE RESIDENTS

The proposed rule also "clarifies" CMS' policies in determining hospitals' FTE resident counts. For example, the proposed rule reiterates that a hospital cannot claim the time spent by residents training at another hospital, even if the original hospital actually incurs the resident training costs at the other hospital.

The propose rule also stresses that hospitals must have proper documentation for the resident time that is claimed on the hospital's Medicare cost report. The proposed rule notes "[a] rotation schedule is the primary documentation that can support the direct GME and IME resident counts but other similar documentation may be acceptable." (71 Fed. Reg. at 24114). CMS emphasizes that hospitals are not permitted to decide for themselves how to determine their FTE counts. As an example, they discuss two hospitals in which residents are training at both hospitals and the two hospitals decide to split the resident counts 50/50. CMS states that this methodology is not acceptable and that each hospital must maintain its own records demonstrating the amount of time that the resident trained at the hospital and, if applicable, the nonhospital site.

The proposed rule reiterates that documentation requirements are set forth at 42 CFR 413.75(d). Proper documentation includes:

- Name and social security number of the resident
- The relevant residency program type and the number of years the resident has completed in all types of residency programs
- The dates the resident is assigned to the hospital and any hospital-based providers (similar to the rotation schedule)
- The dates the resident is assigned to other hospitals, other freestanding providers, and any nonhospital settings
- The name of the entity paying the residents' stipends and benefits
- The name of the medical, osteopathic, dental or podiatric school from which the resident graduated and the graduation date
- Whether the resident is a foreign medical graduate (FMGs) and, if so, documentation that the resident has satisfied the regulatory requirements for FMGs (set forth at 42 CFR 413.80)

[10] CMS must keep in mind that the resident count reflected on a hospital's cost report does not reflect the actual count of residents that spend time in the hospital or qualifying nonhospital site. The full count for which hospitals must keep track of reflects residents doing partial year or even just monthly rotations at that hospital.

The regulations at 42 CFR 413.75(d) also state that the documentation information must be "certified by an official of the hospital and, if different, an official responsible for administering the residency program."

Most, if not all, teaching hospitals use the Medicare intern and resident information system (IRIS) to document and verify resident counts and rotations. The issue of "proper" documentation to allow a hospital to count a resident's time has been the subject of many discussions between teaching hospitals and their fiscal intermediaries. We have communicated our concerns to the CMS central office about the lack of uniform standards around documentation, the burdens associated with duplicative documentation requests, and other issues during the Medicare audit process. We are committed to working with our members and CMS staff to address these issues.

THE OUTLIER PAYMENT THRESHOLD

Under the Medicare inpatient prospective payment system, if the costs of a particular Medicare case exceed the relevant DRG operating and capital payment (including any DSH, IME, or new technology add-on payments) plus an outlier threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case's costs above the threshold calculation.

The outlier fixed-loss cost threshold is set at a level that is intended to result in outlier payments that are between five and six percent. Outlier payments are budget-neutral. Each year the Agency reduces the inpatient standardized amount by 5.1 percent and estimates a cost threshold that should result in outlier payments that equal 5.1 percent.

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus a $25,530 outlier threshold, an increase of 8.2 percent over the FY 2006 threshold of $23,600.

CMS proposes an increase to the threshold even though the Agency estimates that outlier payments for FY 2006 will represent only 4.71 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 4.1 percent of total DRG payments in FY 2005 and, according to the August 12, 2005 final rule, only 3.52 percent of total DRG payments in FY 2004 (70 Fed. Reg. at 47496). Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in all three consecutive years, contrary to the intent of the outlier payment policy.

We believe the FFY 2007 cost threshold must be reduced. CMS relies only on charge inflation to determine projected increases in per case costs, which determines outlier payment outlays. Along with the AHA and FAHS, we conducted an analysis that incorporates both cost and charge inflation, which we believe makes the threshold calculation more accurate and reliable. Using this methodology, the threshold should be

$24,000 for FY 2007. We urge you to review and give serious consideration to the methodology, as described in more detail in the AHA's comment letter.

REPORTING HOSPITAL QUALITY DATA FOR THE IPPS UPDATE

The Hospital Quality Alliance (HQA) was created to develop a process to submit and publicly report hospital performance data. The initial effort was purely voluntary with no financial incentives in place and generated a high level of participation amongst the nation's hospitals.

The Medicare Modernization Act (MMA) introduced the concept of "pay-for-reporting" by requiring hospitals to submit performance data on an initial "starter set" of ten measures, approved by the HQA, or else they would receive a 0.4 percent payment reduction to the annual update. There is currently nearly a 99 percent submission rate from eligible hospitals. The Deficit Reduction Act of 2005 (DRA) introduced a new set of requirements for the Hospital Quality Data Payment Update Program. The DRA calls for additional quality measures to be added to the program and increases the penalty for not reporting the hospital quality performance measures from a negative 0.4 percentage point reduction to the annual payment update to a two percentage point reduction.

The current proposed rule requires that all 21 clinical measures approved by the HQA be submitted in addition to hospitals achieving an 80 percent pass rate in the validation process in order to receive their full payment update. The change from a 0.4 to a 2 percentage point reduction is significant for almost any IPPS hospital and therefore most hospitals will be working towards meeting the proposed requirements. However, the data required for submission is retroactive beginning with the first quarter of CY 2006.

Most hospitals are not collecting all 21 measures and there has been significant discussion about the time and effort required to collect the data for the Surgical Infection Prevention measures. Many hospitals use vendors to collect their performance data and those vendors will be charging hospitals a premium for the additional work associated with collecting data from a prior quarter. In addition to the data collection issue, the measure specifications in January 2006 were different than those currently in use. If vendors do not modify their software to collect the prior data based on the January specifications then the possibility exists that hospitals will fail validation checks based on the change in specifications. Likewise, if the vendors are required to modify their software there would be an added cost to the already high charge of re-abstracting prior data.

The submission of quality data already has a payment penalty for not reporting. It is unfair to impose an additional penalty by requiring hospitals to go back and re-abstract data from a prior quarter. The process should be one that is fair and achievable by everyone and does not create a punitive incentive. The requirements for the payment update should be limited to current and future data collection periods. This would allow

hospitals and vendors to plan accordingly and make the necessary changes to their current reporting scheme.

Appeals Process

Now that the penalty for not reporting has increased significantly, it is imperative that the appeals process be re-evaluated. Currently, hospitals are at a disadvantage if there is a data transmission error or data discrepancy. The reports that are generated to review for data transmission errors are incredibly lengthy and hard to understand for the individual hospital. In addition, they are based on faulty logic since a record can be listed as being successfully transmitted even if critical data elements are missing. We recognize that it is the hospitals and the QIO or vendor that are responsible for proper submission, however the tools being used to assist the hospitals need to be improved or alternative solutions need to be provided.

With regards to the data validation procedure, we commented on the proposed rule in 2004 that it was unacceptable to have the CDAC be the responsible party to abstract the data as well as re-abstract the data if there is an appeal. An objective outside party should be involved to resolve any appeals on behalf of hospitals.

NEW TECHNOLOGY ADD-ON PAYMENTS

The Medicare Modernization Act provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. Yet each year only a few new technologies are approved. Currently, only thee technologies receive add-on payments and only three applications were evaluated by CMS for possible add-on payments in FY 2007. We urge the Agency to review its criteria for approving add-on payments for new technologies to ensure that all innovative and cutting edge services are appropriately reimbursed.

We also urge CMS to raise the add-on payment level for new technologies from 50 percent to 80 percent of the difference between the standard DRG payment and the cost of the procedure using the new technology. This change is supported in the MMA's report language. In addition, it would mirror the current 80 percent marginal cost factor for inpatient outlier payments.

HOSPITAL-ACQUIRED INFECTIONS

Hospital-acquired infections are the focus of many quality improvement efforts at hospitals. National organizations also are focusing on these events. The National Quality Forum (NQF) has created an Infection Committee that is reviewing Hospital Infection measures. Standards of care, evidence-based guidelines and preventive

measures are being put in place to minimize the occurrence of these events. However, these situations can not always be controlled.

The proposed rule aims to identify two conditions that are high cost or volume, that result in the case being assigned to a higher DRG generating a higher payment and could have been prevented by following evidence-based guidelines (71 Fed. Reg. at 24100). The proposal states that hospitals will not receive additional payments for cases that contain a condition that is one of the two identified conditions and it was not present at admission. This significant impact is based on the ability of clinicians to recognize additional diagnoses upon admission that may not be obvious or relevant to the admission. It is not feasible to strictly rely on secondary diagnoses at the time of admission. This rule could result in the denial of many cases where the payment would be warranted. Consequently, the criteria should be modified.

VALUE-BASED PURCHASING

As pointed out in the proposed rule, there are many types of demonstration projects and programs being conducted that are paying hospitals and physicians based on their performance for several quality measures. These programs are important to better understand the critical issues involved in developing a value-based purchasing program. The primary parameters for any value-based purchasing program should ensure that all hospitals will be on a level playing field and those differences among the type of hospitals and patient demographics will not have a negative impact on the hospital's payment.

Because this is such an important issue, the AAMC plans to hold several working-group discussions with constituents in order to develop a well thought out set of recommendations and issues that need to be considered when this type of program is being created. The results of these working-groups will be shared with CMS.

HEALTH CARE INFORMATION TRANSPARENCY INITIATIVE

The proposed rule notes that the Department intends to launch a major health information transparency initiative to make quality and price information more available to the public. Significant progress has been made in making quality information more transparent. The work of the Hospital Quality Alliance (HQA), a partnership of CMS, the AAMC, AHA, and FAHS and others, has led to voluntary reporting and public dissemination of 21 quality measures on the *Hospital Compare* web site and more measures, including those involving patient satisfaction, are planned for the future

While progress has been made regarding quality transparency, similar information on hospital pricing is less accessible. On June 1, the Agency took a step in this direction by publishing Medicare payment information at the national, state, and county levels for 41 DRGs. In the proposed rule, CMS sets forth four options for providing pricing information to health care consumers, including:

- Publishing a list of hospital charges, either for every region of the country or selected regions of the country;

- Publishing the rates that Medicare actually pays to a particular hospital for every DRG, or for selected DRGs, which could be adjusted to account for the hospital's labor market area, teaching hospital status and DSH status;

- Establishing conditions of participation for hospitals that relate to the posting of prices and/or the posting of their policies regarding discounts or other assistance for uninsured patients; and

- Posting total Medicare payments for an episode of care. Under this proposal, CMS could include the costs for an inpatient hospital stay, physician payments, and payments for post-acute care services such as those provided in an inpatient rehabilitation facility, skilled nursing facility or long-term care hospital.

We agree that the public deserves meaningful information about the price of its hospital care. Teaching hospitals are committed to sharing information that will help individuals make important decisions about their health care. Sharing pricing information, however, is more challenging because hospital care is unique. Hospital prices can vary based on patient needs and the services they use. For example, teaching hospitals often treat the sickest and most complex patients which could be reflected in their pricing structure. Prices also often reflect the added costs of hospitals' community service and other mission responsibilities. For teaching hospitals, posted prices might reflect additional costs associated with their teaching and research missions, caring for the under- and uninsured, and stand-by capacity costs. However, with careful thought and analysis these issues can be addressed so that pricing information can be comparable across hospitals.

We believe the position statement recently released by the AHA merits serious consideration. This "roadmap" document notes that 32 states already require hospitals to post pricing information and encourages the Department to provide incentives for states to improve transparency at the state and local level. Because most patients have some form of insurance, providing information about patients' "out of pocket" costs also is important, particularly before a service is provided. We concur with the AHA position that more research is needed to better understand the information patients want and need to better make health care decisions.

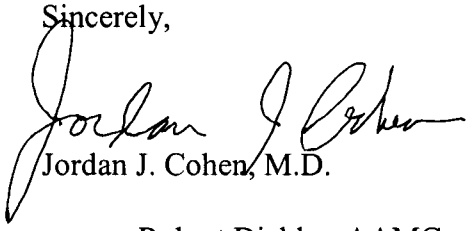
The AAMC is committed to working with the Department, insurers and other hospital organizations to ensure that consumers are provided meaningful information about both quality and costs. It is important that such efforts be coordinated so that hospitals are not spending unnecessary time providing the same information in multiple formats.

CONCLUSION

Thank you for this opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve the academic health care community.

If you have questions concerning these comments, please do not hesitate to contact Robert Dickler, Senior Vice President, Health Care Affairs, or Karen Fisher, Senior Associate Vice President. These individuals may be reached at (202) 828-0490, or rdickler@aamc.org and kfisher@aamc.org.

Sincerely,



Jordan J. Cohen, M.D.

cc: Robert Dickler, AAMC
Karen Fisher, AAMC

Attachment A

Attachment A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

SEP 2 4 1999

Mr. B. Scott McBride
Vinson & Elkins L.L.P.
2300 First City Tower
1001 Fannin Street
Houston, TX 77002-6760

Dear Mr. McBride:

This is in response to your letter regarding the calculation of full time equivalent (FTE) resident counts in nonhospital settings for determining direct (GME) and indirect (IME) graduate medical education payments. You specifically inquired about Health Care Financing Administration's (HCFA) interpretation of "patient care activities" in relation to the time residents spend in nonhospital sites.

HCFA interprets the phrase "patient care activities" broadly to include any patient care oriented activities that are part of the residency program. As you stated in your letter, this can include resident participation in "1) the direct delivery of patient care, such as clinical rounds, discussions, and conferences, and 2) scholarly activities, such as educational seminars, classroom lectures, research conferences, patient care related research as part of the residency program, and presentations of papers and research results to fellow residents, medical students, and faculty." Therefore, as long as the residents are primarily involved in patient care oriented activities and other program requirements are met, a hospital may include other educational activities as part of the entire time spent by residents in nonhospital settings and include this time in its FTE count and GME/IME payment calculations.

If you have further questions, please call Rebecca Hirshorn at 410-786-3411 or Michelle Lefkowitz at 410-786-5316 of my staff.

Sincerely,

Tzvi M. Hefter
Director
Division of Acute Care
Plan and Provider Purchasing Policy Group

Attachment B

Attachment B

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June 8, 2006

Karen S. Fisher
Association of American Medical Colleges
2450 N Street, N.W.
Washington, DC 20037

Re: Inpatient PPS Rule for FY 2007

Dear Ms. Fisher:

You have asked that I review and comment on the recent proposed inpatient PPS rule issued by the Centers for Medicare and Medicaid Services ("CMS") relating to medical education and, specifically, the agency's decision to exclude most didactic time from the resident FTE counts. *See* 71 Fed. Reg. 23996, 24114-24115 (April 25, 2006). I am happy to do so.

Introduction

In the proposed rule, the agency states that it is "clarifying our policy" to make clear that residents' time spent in nonpatient care activities, even if part of an approved program, "cannot be included in a hospital's direct GME or IME FTE resident count." As support, the agency relies, for direct GME, on language in 42 U.S.C. § 1395ww(h)(4)(E) providing that, in the nonhospital setting, "*only time spent in activities relating to patient care* shall be counted ..." in the FTE calculation and, for IME, on language in 42 U.S.C. § 1395ww(d)(5)(B)(iv) providing that "all the time spent by an intern or resident in *patient care activities* under an approved medical residency training program ... in a nonhospital setting shall be counted" in the FTE calculation. The agency then states that didactic and "scholarly" activities, such as educational conferences, journal clubs, and seminars, do not qualify as "activities relating to patient care." While CMS acknowledges that it has never defined in regulations what constitutes patient care activities for direct GME or IME purposes, it notes that the term has a well-established meaning in the Medicare program. The "plain meaning of patient care activities" CMS states, does "not encompass didactic activities" but, instead, "refers to the care and treatment of particular patients, or to services for which a physician or other practitioner may bill." In its proposal, CMS recognizes one exception to its didactic time policy, an exception applicable to direct GME payments attributable to residents working in the

hospital setting. Subject to this one exception, however, no didactic time may be included in the FTE count under CMS's proposal.

Analysis of CMS's Proposal

I disagree with CMS's proposal and with the analysis upon which it is based. First, as explained below, the analysis takes an overly rigid view of what constitutes patient care activities. Such activities are not limited to those in which there is the care and treatment of particular patients, that is, services and their related costs for which a physician or other practitioner may bill. To state otherwise is to disregard CMS's longstanding interpretations of the term "cost related to patient care," the term upon which CMS bases much of its analysis. Second, CMS's position fails to recognize the very close nexus between the didactic activities at issue and the delivery of patient care, a nexus stressed in the structure of graduate medical education programs. Finally, the policy proposed by CMS, insofar as it relates to the counting of residents in the hospital setting for purposes of the IME calculation, is not supported by the statute and is contrary to the purposes behind the IME provision.

1. CMS's Proposed Policy Regarding Patient Care Activities Sharply Departs From Existing Policy and Interpretations.

As an initial matter, as stated above, CMS's position reflects an overly rigid construction of "patient care activities," a construction that is inconsistent with over 40 years of CMS policy. CMS asserts in the proposed rule that, in order for there to be a patient care activity, the service must be one that refers to the "care and treatment of particular patients." In other words, CMS suggests that only direct patient care and the direct costs relating to that care may be recognized. Medicare's own regulations and policy interpretations, however, contradict this position. As recognized in the proposed rule, Medicare's guiding regulation in determining whether a cost is related to patient care is 42 C.F.R. § 413.9, in which costs related to patient care are defined broadly to include both "direct and *indirect* costs of providers of services." 42 C.F.R. § 413.9(b). These costs include costs that are "appropriate and helpful" in maintaining the operation of patient care facilities and operations, and typically are costs that are "common and accepted occurrences" in the field of the provider's activity. 42 C.F.R. § 413.9(b)(2). These costs include all necessary and proper expenses incurred in furnishing services, such as administrative costs, maintenance costs and normal "standby" costs. 42 C.F.R. § 413.9(c)(3). In short, CMS has defined costs related to patient care in broad terms to include far more than just "direct" patient care and the "direct" costs of that care.

CMS's other policy statements underscore this breadth of definition. In the Provider Reimbursement Manual ("PRM"), Chapter 21, entitled "Costs Related to Patient Care," CMS describes those activities and costs "related to patient care," interpreting the

language of 42 C.F.R. § 413.9. Those costs, as described in the PRM, include costs incurred in conjunction with such things as:

- Employee Travel. PRM § 2105.6.
- Start-up costs. PRM § 2132.1.
- Utilization review, including the purchase of data and statistics. PRM § 2126.4.F.
- Advertising costs incurred in connection with the provider's public relations activities. PRM § 2136.1.
- Memberships in professional, technical and business related organizations. PRM § 2138.1.
- Memberships in organizations that promote civic objectives. PRM § 2138.2.
- Meals served to hospital personnel. PRM § 2145.
- Parking lots used by physicians and visitors. PRM § 2107.1.

These are just a few of the categories that are recognized as allowable in the PRM, and these costs are plainly not costs related to services or activities for which a practitioner or physician could directly bill, as CMS has asserted is the standard.

Even more germane to the question of the allowability of didactic time—time spent by residents in conferences, seminars, and journal clubs—are provisions in the PRM that specifically address time spent in similar activities by physicians and other hospital employees. Notably, the PRM specifically allows costs that a provider claims in connection with the following activities:

- Time spent by physicians attending conferences. PRM § 2108.1.
- Time spent in orientation and on-the-job training. PRM § 2128.
- Activities involving professional contacts with physicians, hospitals and the like to discuss the provider's covered services. PRM § 2136.1.

- Meetings and conferences, including meals, transportation, registration and associated costs where the purpose is to disseminate information for the advancement of patient care or efficient operation of the facility. PRM § 2138.1.

- Meetings and conferences, including meals, transportation, registration and associated costs where the purpose of such meetings and conferences is the promotion of civic objectives. PRM § 2138.2.

- Provider-paid educational courses benefiting the employee's interest. PRM §§ 2144.4; 2144.6.

- Physician time spent in training of staff. PRM § 2182.6.

All of these activities have long been recognized by CMS as "related to patient care," yet none of these involves "the care and treatment of individual patients" or "services for which a physician or other practitioner may bill," the measures that CMS incorrectly asserts should apply in determining a patient care nexus. 71 Fed. Reg. at 24,115. In summary, then, the didactic activities in question here are plainly patient care activities under CMS's own application of that term and are fully consistent with the examples set out in the PRM.

2. Didactic Time Has a Close Nexus to Patient Care.

Time spent in journal clubs, conferences, seminars and the like may not be time that a physician or practitioner could bill to Medicare as a discreet patient care service, but they do support the patient care activities of the hospital and, as such, are related to patient care. Indeed, that support is often quite closely related to the care of individual patients. If one speaks to teaching physicians and residents, one learns that the academic content of resident seminars and conferences (collectively, "conferences") often are based on the actual patients receiving care at the hospital at the time of the conference and have, as a primary goal, improving care provided to those patients and to others with similar medical problems. The residents discuss the medical issues encountered by actual patients and the best course of treatment for those patients, which treatment plans are then implemented. The same is true for journal clubs and other didactic activities, for which the focus at each presentation is typically on problems presented by actual patients in the hospital setting. These are often not theoretical patients, and the topics being discussed are not abstract presentations. Instead, the didactic activities are related to real life problems faced by the residents in their treatment of their real life patients. The activities are intended to instruct the residents while simultaneously providing high quality patient care.

These points—and particularly the relationship of didactic activities to patient care—are well recognized by academic medicine. Section II of the *Graduate Medical Education Directory*, 2005-2006, states as follows:

> The education of resident physicians relies on an *integration of didactic activity* in a structured curriculum *with diagnosis and management of patients* under appropriate levels of supervision and scholarly activity aimed at developing and maintaining life-long learning skills. The quality of this *experience is directly related to the quality of patient care*, which is always the highest priority. *Educational quality and patient care quality are interdependent* and must be pursued in such a manner that they enhance one another.

Directory at pp. 9-10 (emphasis added). Thus, as this paragraph recognizes, didactic activity is "directly related to the quality of patient care." For CMS to take a different position is to ignore what has long been recognized by teaching hospitals, teaching physicians, residents, and the various accrediting organizations themselves.

3. CMS's Statements Regarding IME Are Inconsistent With the Statute.

Finally, even if one were to accept CMS's analysis regarding didactic activities furnished in nonhospital sites, that analysis would not hold together when applied to didactic activities furnished in hospital settings. CMS has recognized this when it comes to direct GME payments, and it does not propose to disallow didactic activities from the FTE count for direct GME payments related to residents training in hospital settings. It does propose, however, to disallow FTE time from the *IME count* when residents are training in didactic activities in the hospital, as compared to the nonhospital, setting. Such a position, I submit, is contrary to the statute and its legislative history. First, as it relates to the statute, the IME provisions at 42 U.S.C. § 1395ww(d)(5)(B) impose no requirement that time spent in didactic activities in the hospital be related to patient care. The "patient care activities" requirement, by statute, relates solely to resident training that takes place in nonhospital settings. 42 U.S.C. § 1395ww(d)(5)(B)(iv). One should presume that when Congress imposes a "patient care activities" requirement for nonhospital training but does not do so for hospital training, Congress does not intend for there to be such a requirement for the hospital training. This is true for direct GME payments, and it is equally true for IME payments. Therefore, even if didactic activities were not deemed to be "patient care related," which I believe would be incorrect, no patient care requirement is imposed by the statute for "in-hospital" training.

Moreover, to exclude didactic time from the IME calculation would be inconsistent with Congress's purposes in enacting that provision. Congress's stated

purpose for implementing the IME provision was to address factors that contribute to the higher costs incurred by teaching hospitals, which factors include such things as the greater severity of patient illness, the specialized services offered by teaching institutions, and the additional costs associated with training residents resulting from such things as the ordering of additional tests and extra staffing demands. If a resident is involved in didactic activity, these costs are in no way reduced. During the time that residents spend in didactic activities, the patients remain just as ill as they were before; the hospital continues with its resident-related inefficiencies; the hospital continues to provide specialized services; and the services are just as intense. Thus, all of the costs that the IME adjustment is intended to compensate continue unabated no matter what the resident is doing. Given this, the proposed exclusion of didactic time from the IME calculation is inconsistent with the purposes behind the IME adjustment.

Conclusion

For all of these reasons, I believe, the proposed CMS policy is misguided. It misreads the statute. In so doing, it fails to recognize the relationship of didactic activities to patient care and establishes, instead, a standard that does not encompass the many activities required for optimal patient care. Accordingly, the AAMC should object to the proposal and strongly recommend that it be abandoned.

Sincerely,

Thomas W. Coons

TWC/mla

169

Wake Forest University Baptist
MEDICAL CENTER

Len B. Preslar, Jr.
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Telephone: (336) 716-4750
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June 12, 2006

HAND-DELIVERED

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-1488-P
P. O. Box 8010
Baltimore, MD 21244-1850

Dear Dr. McClellan:

Subject: CMS-1488-P, Medicare Program; Resident Time in Patient Activities

North Carolina Baptist Hospital (NCBH) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006). NCBH is part of Wake Forest University Baptist Medical Center, an academic health system comprised of 1,106 acute care, psychiatric, rehabilitation and long-term care beds located in the northwestern section of North Carolina, the region's main tertiary referral center.

NCBH strongly urges CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom

lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care

NCBH believes journal clubs, lectures and seminars are a time-honored component of the education of a physician and harkens back to the post-Flexnerian era. Otherwise, physicians would be trained in a trade school; precisely as Flexner observed and reversed, thus improving the education of the physician in the early 20th century. With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

At NCBH, didactic time is essential to the vital functioning of our trauma service, which typically cares for 40-70 patients a day. It has a didactic conference every morning where pertinent patient care issues are brought up for discussion, teaching takes place, and a plan of care developed. Once the subject matter is covered, it saves the supervising physician the time of having to discuss similar care issues on a daily basis on other patients. This adds vital efficiency to the functioning of the trauma service, and allows for a large number of patients to be cared for by the service.

Additionally, many of the residencies require educational conferences, such as cardiology cath conference and cardiothoracic surgery, neurosurgery and interventional neuroradiology or radiation oncology and all the pathology discussion at multidisciplinary tumor conferences. These are all case-based, meaning that current patients are presented to discuss management strategies or diagnostic dilemmas. This is another example where residents' skills are being increased while direct patient care is being better performed.

Whether one labels these teaching sessions "didactics" or "multidisciplinary patient management conferences" becomes semantics. The point is the supervising physician looks for every opportunity, in whatever physical setting for the "teachable moment" to review a critical point or two to hone the learner's skills. In this manner, the resident's skills and patient care he/she subsequently delivers are simultaneously improved.

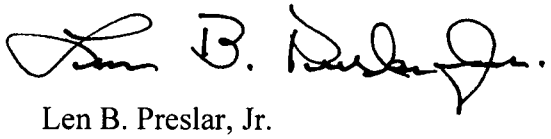
Also, during morning report on the internal medicine service, all new admissions are presented to a chief resident at the start of the day. Patient care plans are discussed with the team and teaching points are highlighted. If time allows, short presentations are made on topics arising from recent patient management questions. In this manner, the entire team including nighttime "covering" residents can quickly link clinical management to evidence based medicine.

Recommendation:

To reiterate, NCBH believes the proposed rule is in direct conflict with the Accreditation Council for Graduate Medical Education (ACGME)/Residency Review Committee (RRC) regulations which clearly delineate the curriculum for residency training and recognize the necessity of didactic teaching We urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

If you have any questions concerning these comments, please contact Joanne C. Ruhland, Vice President Government Relations at jruhland@wfubmc.edu or 336-716-4772.

Sincerely,



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170

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June 12, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1500-P
P. O. Box 8010
Baltimore, MD 21244-1850

HAND DELIVERY

Dear Dr. McClellan:

Subject: CMS-1488-P and P2, Medicare Program
Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007; Proposed Rule

North Carolina Baptist Hospital (NCBH) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Service' (CMS) proposed rule entitled, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed. Reg. 23996 (April 25, 2006). NCBH is part of Wake Forest University Baptist Medical Center, an academic health system comprised of 1,106 acute care, psychiatric, rehabilitation and long-term care beds located in the northwestern section of North Carolina, the region's main tertiary referral center.

NCBH commends CMS for its ongoing efforts to ensure adequate reimbursement for all clinical services. Moreover, it recognizes the extremely complex issues involved in establishing appropriate reimbursement for procedures performed in the inpatient setting. However, NCBH is extremely concerned that these proposed sweeping changes will have a negative financial impact on our institution and believes further study, and likely changes, to the proposed rule are needed.

Background:

In the Notice of Proposed Rulemaking (NPRM), CMS is proposing to make the most significant changes to the calculation of DRG weights and the patient classification system since the beginning of the Inpatient Prospective Payment System. The proposed changes appear to have their roots in the Medicare Payment Advisory Commission's (MedPAC)

2005 Report to Congress on Medicare payments for a certain subset of "specialty" hospitals. The MedPAC report raised concerns that the specialty hospitals were selecting the most profitable cases in their area and leaving the other acute care hospitals with less profitable services. Rather than addressing this issue of specialty hospitals in independent fashion, MedPAC recommended changing the payments for ALL acute care hospitals to reduce the incentives in the overall inpatient payment system that fueled the growth of specialty hospital facilities.

Proposed Changes:

Specifically, CMS proposes major changes to the DRG weights for FY 2007—use of hospital-specific relative values (HSRVs) and a modified version of cost-based weights rather than charged-based weights. The combination of these two changes is referred to as the hospital-specific relative value cost center (HSRVcc) methodology. CMS also proposes major changes to the patient classification system, refining the DRGs to account for patient severity, through the creation of a new patient classification system called consolidated severity adjusted DRGs (CS-DRGs), with implementation likely in FY 2008.

Analyzing the Proposed Changes:

Despite the obvious complexity associated with the methodology, combined with the major financial impacts associated with the resultant DRG weight changes, NCBH, along with other hospitals, was given only 60 days to review and comment on the proposed rule changes. During this period, NCBH has worked with the American Hospital Association (AHA), the Association of American Medical Colleges (AAMC), participated in many telephone conferences, and has conducted numerous analyses to try to understand the policy goal of the proposals, the underlying methodologies, and the resulting impacts.

Overall Impact of the Proposed Changes:

These analyses have revealed the areas negatively affected to include Cardiac Surgery, Interventional Cardiology, General Cardiology, Orthopedics, and Vascular. The payment decrease expected from these services lines will total $6 million dollars. Specifically, we are estimating the following amounts for each service line: Cardiac Surgery – $1.2 million; Interventional Cardiology - $4.2 million; General Cardiology - $446,000; Orthopedics - $86,000; and Vascular - $213,000. Patients in these areas account for over 37% of our annual Medicare discharges and a $6 million payment reduction is very significant for our institution. With a growing elderly population, patients needing Cardiac and Orthopedic services will only continue to increase. Because of the age of the cost data, the proposed methodology does not adequately account for the cost related to the newest technology that hospitals are providing to Medicare patients.

DRGs from which we may see some payment increase account for 40% of our annual discharges. These aggregate payment increases fall substantially short of covering the losses stated above. This is not a budget neutral event. The remaining 23% of our discharges will remain neutral in terms of payment changes.

Concerns with the Proposed Rule

NCBH does not oppose moving from a charge to a cost-based DRG weighting methodology, but believes that a one-year postponement is necessary to allow for further analyses. This is necessary in order to address our concern that the new proposed DRG weights would be based on cost data that are three to five years old. These data are neither current nor accurate and do not include the costs associated with many important and commonly used technologies. Also, the hospital charges are not weighted by volume, so a smaller hospital of 50 beds would carry as much weight as our 1,106 beds.
CMS needs to address these data and computation issues to ensure that the best possible methodology is implemented.

We also support refinement of the DRGs, but believe that the proposed consolidated severity-adjusted DRGs (CS-DRGs) require further examination and likely modifications before implementation. Severity adjustments have potential, but must account for both complexity and severity, not just severity. As a major teaching hospital, it is important to us that the DRG classification system reflect those cases that involved the sickest and most complex Medicare patients and that the correct assignment is made so that the DRGs adequately reflect the resources needed to treat these patients. Hospitals must be given appropriate information on the method and impact of any new severity adjustment system and given appropriate time to evaluate and comment on them.

The impact of adopting cost-based methods and severity adjustment at different times should be addressed. NCBH believes that these changes should be implemented simultaneously to ensure equity and minimize payment volatility for our institution. Otherwise, we may be "whipsawed" by shifting dollars in opposite directions in succeeding years.

Finally, because the potential impact of these changes is monumental, there should be a significant transition period to implement these changes. There is historical precedence in the Medicare program on which we base this comment. Changes that were accompanied by transitions include: move to a PPS for capital (10 years); implementation of the operating IPPS (four years); eliminating day outliers (four years). The proposed changes will result in a redistribution of over one billion dollars and therefore requires a significant transition period.

NCBH remains committed to working with CMS and other health care organizations, such as the AHA and the AAMC to ensure that Medicare beneficiaries have continued access to high quality, efficient and effective health care. We look forward to a continuing dialog as it relates to this proposed rule.

If you have any questions concerning these comments, please contact Joanne C. Ruhland, Vice President Government Relations at jruhland@wfubmc.edu or 336-716-4772.

Sincerely,

Len B. Preslar, Jr.

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171

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JUN 12 2006

J. Brian Munroe
Vice President
Federal Affairs

VIA HAND-DELIVERY (ORIGINAL AND TWO COPIES)

June 12, 2006

The Honorable Mark McClellan, MD, Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1488–P
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

RE: File Code CMS–1488–P
Comments on Proposed Rule: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, NPRM CMS-1488-P (42 C.F.R. Part 409, 410, et al.)(71 Fed. Reg. 23996, April 25, 2006)

Dear Dr. McClellan:

WellPoint, Inc. is pleased to have the opportunity to comment upon the impact of the proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2007 rates appearing in the *Federal Register*, Volume 71, Number 79, on April 25, 2006.

WellPoint, Inc. is the largest publicly traded commercial health benefits company in terms of membership in the United States. WellPoint, Inc. is an independent licensee of the Blue Cross Blue Shield Association and serves its members as the Blue Cross licensee for California; the Blue Cross and Blue Shield licensee for Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri (excluding 30 counties in the Kansas City area), Nevada, New Hampshire, New York (as Blue Cross Blue Shield in 10 New York City metropolitan counties and as Blue Cross or Blue Cross Blue Shield in selected upstate counties only), Ohio, Virginia (excluding the Northern Virginia suburbs of Washington, D.C.), Wisconsin; and through UniCare Life and Health.

We appreciate the opportunity to participate in CMS' formulation of these important changes to Medicare's hospital payment methodologies. As the largest hospital payer, Medicare's payment rates and methodologies have major impacts on hospital behavior. Private health insurance carriers rely, to some extent, on Medicare payment methodologies in their hospital contracting efforts. In addition, health insurers must contend with hospital rate demands that are affected by the level of Medicare payments. The effectiveness of health insurers' hospital contracting efforts, in turn, affects Medicare payment policies, because hospitals that can secure

high private sector rate increases can at least partially escape the efficiency incentives provided by the Medicare DRG system. If hospital costs rise faster than Medicare's payments, the Medicare payment-to-cost ratio declines, with consequent negative effect on the credibility of the Medicare DRG system as a reasonable payment mechanism. We believe that CMS and the health insurance industry have congruent objectives in providing hospitals with incentives for greater efficiency.

Most often, commercial insurers such as WellPoint reimburse hospitals at rates higher than Medicare. This cost-shift has been a factor in limiting the affordability of health care for Americans insured through private sector employers and insurers. These payment differentials have been brought into sharper focus by CMS's recent publication of cost information for certain inpatient procedures.

Although we endorse CMS' efforts to improve the accuracy of DRG weights and to increase the sensitivity of the DRG methodology to differences in patient severity levels, we believe that CMS' proposed changes require more study and analysis before they can be implemented in a fashion that affords all affected parties a reasonable amount of time to analyze their impacts and make appropriate changes in business practices. WellPoint is concerned that the proposed changes will introduce a significant amount of disruption to the commercial health insurance marketplace, driving up healthcare costs and causing marketplace confusion, without providing for an adequate transitional period. Furthermore, the proposed changes in DRG reimbursement will have the unintended consequence of rewarding complications of care and do not support CMS's major strategic direction to improve the quality of care delivered in U.S. hospitals.

Accordingly, we urge CMS to postpone implementation of both the DRG weight changes and the severity-adjusted DRG methodology until October 1, 2007, and to provide the hospital and health insurance industries and other interested parties with the maximum possible advance notice of the specific changes, and their hospital-specific impacts, to ensure that all affected parties can make appropriate responsive adjustments in their business practices.

Attached to this letter are more specific comments regarding key components of the proposed regulation.

If CMS seeks additional clarification or amplification of our comments, please feel free to contact me at (202) 628-7840. We welcome the opportunity to further discuss our vision and to work with CMS to advance the quality of health care services in our nation's hospitals.

Sincerely,

J. Brian Munroe
Vice President, Federal Affairs

Attachment – WellPoint Comments

June 12, 2006

WellPoint, Inc. Comments on
Proposed Changes to the Medicare Program
Hospital Inpatient Prospective Payment Systems
and Fiscal Year 2007 Rates (42 C.F.R. Part 409, 410, et al.)
(71 Fed. Reg. 23996, April 25, 2006)
File Code CMS–1488–P

A. DRG Reclassifications

We appreciate the fact that CMS proposes to make only minor changes in the DRG classification system for fiscal year 2007 and to adopt consolidated severity-adjusted DRGs for fiscal year 2008. However, CMS also reserves the right to implement the proposed severity-adjusted DRGs, or an alternative system, effective October 1, 2006. While we agree that improvements to the DRG classification system are needed, any such changes should have a longer compliance lead time to ensure that hospitals and other affected parties, such as the private insurance industry, have sufficient time to plan for the changes and to adjust their business practices accordingly. If CMS implements the new methodology before the health insurance industry has time to analyze the impact, renegotiate hospital contracts, and implement required system and contractual changes, either healthcare costs will soar or confusion will prevail.

Many private health insurance company contracts use the CMS DRG Relative Weights (RWs) as the payment basis for inpatient services delivered to members under private health insurance plans. These contracts are typically negotiated based on a fairly static assumption of CMS DRGs (including the classification and weights). The proposed redistribution will disrupt virtually every such contract because of the different type of services consumed by members covered under private health insurance. Specifically, the ratio of medical admissions to surgical admissions for Medicare beneficiaries is about 5 to 1, whereas the ratio for the privately-insured population is about 2 to 1. This means that the redistribution will much more significantly impact network contracts with health insurers that are linked to CMS DRGs and weights.

Consider the example below. In this example, a 25% reduction on surgical cases is balanced by a 21% increase for medical admissions and produces a budget neutral impact for Medicare admissions. However, for a commercial population the exact same payment change produces a 10.77% reduction, due to the different relativity between medical and surgical admissions.

	Medicare		Commercial	
	Medical	**Surgical**	**Medical**	**Surgical**
Current				
Ave. $ per admit	$ 10,000	$ 20,000	$ 10,000	$ 20,000
Admits	2.4	1	0.9	1
Revenue	$ 24,000	$ 20,000	$ 9,000	$ 20,000
Total Revenue	$ 44,000		$ 29,000	
Proposed	**21%**	**-25%**	**21%**	**-25%**
Ave. $ per admit	$ 12,084	$ 15,000	$ 12,084	$ 15,000
Admits	2.4	1	0.9	1
Revenue	$ 29,002	$ 15,000	$ 10,876	$ 15,000
Total Revenue	$ 44,002		$ 25,876	
Net Impact	0.0%		-10.77%	

It is clear that the greater proportion of surgical cases in commercial populations will act as a magnifier of the CMS impact.

The redistribution of Medicare dollars will produce winners and losers within the hospital market. The hospitals that realize Medicare revenue losses will aggressively seek to maximize their private sector revenue, most likely through contract terminations and renegotiations. This may also impact Medicare Advantage networks, as hospitals will seek to link their participation in managed Medicare programs to renegotiating the terms of their commercial contracts.

In order to minimize the disruption to contracts between hospitals and health insurers, CMS needs to publish the revised DRG RWs and changes to the Medicare base rates as soon as possible, as well as provide greater lead time before implementing the changes. Health insurers will need to model the impact to many of their individual hospital contracts.

1. Differences in Severity Levels

We believe that the work done by MedPAC and CMS sufficiently demonstrates the need to refine the DRG system to capture severity level differences. We agree with CMS that hospitals' service offerings should respond to patients' medical needs rather than to unintended financial incentives embedded in the DRG classification system. Currently, it appears that hospitals are positively or negatively affected by their mix of patients within DRGs, with the less severely ill patients generally more profitable than the more severely ill. These unintended effects result, in part, from the current DRG

classification system's inability to distinguish between patients grouped into the same DRGs. We believe that the proposed move to a more sophisticated DRG grouper will improve the equity of the payment system across hospitals and will ensure that hospitals shape their clinical offerings based on patient needs rather than on financial incentives that drive excess utilization of certain services.

2. Choice of DRG Groupers

The severity-adjusted DRGs that were used by CMS in its modeling efforts were based on the APR DRGs designed and marketed by 3M. We believe that it is essential that any severity-adjusted grouper CMS adopts be based on clinical logic accessible to all interested parties, and that the grouper be made available for sale by CMS at a reasonable price. This approach will ensure that the merits and demerits of the new grouper logic can be assessed by independent parties, who can then contribute to CMS's ongoing annual efforts to revise the Medicare grouper to respond to changes in medical practice. We believe that CMS should consider other possible groupers available from companies other than 3M, such as the severity-adjusted grouper offered by HSS, Inc. However, it is most important that any new grouper be open to public scrutiny and that it be available at a fair price from a number of sources--i.e., from CMS and from private vendors.

3. Case Mix or Coding "Creep" Effects

As CMS has acknowledged, the introduction of DRGs in 1983 was followed by a period during which increases in hospitals' case mix index was substantially driven by coding improvements rather than increases in underlying patient complexity. Changing DRG groupers to increase their sensitivity to severity differences will create the possibility of case mix index escalation (or "creep"), reflecting coding practice changes rather than a change in actual case mix levels. For example, when the State of Maryland adopted the APR DRG grouper as the basis of its all-payer hospital payment system, it experienced large coding effects as well as unwarranted payment increases, particularly at academic medical centers. Coding creep will inappropriately increase Medicare hospital payments at hospitals engaging in coding practices that fail to reflect actual case mix changes. While CMS has proposed including a rate offset designed to counteract the impact of anticipated coding creep, this control mechanism is blunt, because it would presumably be applied on an across-the-board basis. Such an approach unfairly takes money away from hospitals not generating coding creep while failing to take sufficient funds from those hospitals that do generate coding creep. We suggest that CMS develop a technique for measuring the actual degree of coding creep at particular hospitals, and make consequent rate adjustments hospital-specific rather than unilateral.

June 12, 2006
WellPoint, Inc. Comments

CMS could improve upon its proposed unilateral "creep" offset by encouraging hospitals to implement improved coding before their coding changes will affect their Medicare payments. We recommend that CMS announce in the Final Rule for fiscal year 2007 that it plans to adopt the proposed severity-adjusted DRG grouper, or a similar approach, for fiscal year 2008. We further suggest that CMS announce that it will use MedPar data from fiscal year 2007 to compute the ratio of each hospital's case-mix index (CMI) using the previous non-severity adjusted DRGs, to the CMI that would have resulted from use of the severity-adjusted DRG grouper. Further, we recommend that CMS announce that it will apply a hospital-specific adjustment reflecting this CMI relationship to the base operating and capital amounts that will be used when CMS implements its new severity-adjusted grouper. The adjustment should be designed to remove the "undercoding" effect on a hospital-specific basis. The effect of this approach would be to give hospitals strong financial incentives to fully code their cases, in accordance with the increased sensitivities of the severity-adjusted grouper, during fiscal year 2007, before the coding changes affect payments, rather than to wait to make the coding changes when they will affect Medicare payments. This approach would also give CMS a method of implementing payment adjustments reflecting hospital-specific coding differences, rather than making unilateral adjustments that unfairly reward or penalize individual hospitals.

Such an approach could also be combined with a case mix "governor" that reflects historical Medicare case mix changes. Any excess increase in nominal case mix levels across the industry could be removed from rates in total by using hospital-specific adjustments reflecting individual hospital coding practice changes.

The ratio of medical versus surgical cases differs substantially between the Medicare and commercial populations. Thus, the overall impact calculated by Medicare will be substantially different for the private sector, especially for those hospitals with higher ratios of surgical/total private patients. We expect that hospitals that are negatively affected will seek to adjust payment rates with their contracted health insurers and that insurers may be faced with a substantial number of unplanned renegotiations which could be disruptive to provider networks.

This severity-adjustment methodology change will be complicated by needed hospital coding changes. The coding demands of the proposed severity-adjusted grouper are significantly greater than those that are made by the existing CMS version, because codes that currently do not affect DRG assignments will have impacts under the new grouper. With the change from 526 to 861 DRGs, coders will need substantial additional training and the coding tasks will become more challenging and time consuming. There will be a substantial learning curve for coders and this transition will likely delay coding and submission of claims to both CMS and to commercial payers, putting a strain on hospital cash flow.

4. DRG Incentives

We would like to raise two other points regarding the DRG reclassifications and the design of a new grouper. Specifically, a key design feature of the DRG system is that greater reimbursement is provided for more complex medical treatment. This approach encourages hospitals to provide expensive services—such as high technology treatment or surgical interventions—that may or may not be more effective than less expensive alternatives such as medical management. The proposed severity-adjusted DRGs incorporate this incentive, whereas other severity-adjusted DRG classification systems, such as the APS DRGs offered by HSS, Inc., assign severity levels only on the basis of clinical conditions, rather than on the basis of clinical conditions and treatment decisions. We believe that CMS should review the effects of the existing reimbursement bias toward more expensive interventions, especially in the light of the absence of incentives to physicians to make treatment decisions sensitive to cost and quality.

CMS should also adjust the DRG grouper, or the weights accompanying it, to prevent Medicare from making inappropriately high payments for avoidable patient hospital-acquired complications. Currently, patients that acquire infections or undergo other complications occurring during their inpatient stays are often classified into DRGs reflecting the additional costs of the complications. If the complications were avoidable, these additional payments unwittingly subsidize low quality medical care. Of course, some complications are unavoidable and not signs of poor quality. CMS could adjust the DRG weights to reimburse only some portion of the additional costs of hospital-acquired complications. This approach, if implemented on a budget neutral basis, would reward hospitals with higher quality and spur all hospitals to reduce in-house complication levels.

B. HSRV Weight Changes

We believe that the work performed by MedPAC and the additional analyses carried out by CMS amply demonstrate that the current DRG relative weighting system, based on relative charges across DRGs, has been distorted by differences in charge markups across hospitals and across departments within hospitals. This weight distortion has led to significant differences in profitability ratios across services, and within services by DRG. The fact that some services and DRGs are systematically more profitable than others creates inappropriate incentives for hospitals to specialize in highly profitable services and to restrict their service offerings with relatively low profit expectations. We agree with CMS that hospitals should face neutral financial incentives across DRGs and that they should provide those services needed by their communities rather than those services that have the best profit potential.

June 12, 2006
WellPoint, Inc. Comments

The adoption of relative value, cost-based weights will do much to remove the distortions that have crept into the DRG system over time due to its reliance on standardized charges as the basis of the DRG weighting system. We urge CMS to adopt relative value, cost based weights as part of its adjustment of the DRG system. However, we have some concerns that are expressed in the following more specific comments.

1. Markup Differences Within Hospital Departments

CMS and MedPAC have shown that a greater mark-up in charges exists for ancillary than for routine services, and that this difference skews the charge-based DRG weights upward for surgical services and downward for medical services. The "weight gain" for medical services and the "weight loss" for surgical services resulting from the adoption of CMS's proposed weight changes is appropriate, because it would reduce the current biases in the DRG system favoring the production of surgical rather than medical services. The increase in the percentage of DRGs that would have relative profitability ratios close to 1.0 is good evidence of the beneficial effects of the proposed weight changes.

As CMS and MedPAC have acknowledged, charge markups vary not only across hospital departments but within departments as well. The recent MedPAC report entitled "A Study of Hospital Charge Setting Practices" (December 2005) and WellPoint's own experience confirm that hospital charges often bear only a loose and inconsistent relationship to costs on a detailed, item-by-item basis within departments. Although recently hospitals have paid more attention to aligning their outpatient charges with those of their competitors, and with estimates of costliness—often by reference to CPT-4/HCPCS values—their prices for inpatient items are still set, in many instances, by inflating prior charges that were themselves established in a non-systematic way. Accordingly, neither the use of the simplified, weighted cost center approach to the adjustment of charges to costs, nor the use of the more detailed, department-specific cost-to-charge ratios, as recommended by MedPAC for the establishment of DRG weights, would address the problem of large and inconsistent charge markups within departments.

Establishing credible DRG weights that reflect solid estimates of underlying costs is an important task for CMS to pursue, and the weight changes that CMS has proposed are a valuable step in the right direction. We suggest that CMS could improve the credibility of the proposed DRG weights, and their ability to remove biases in the relative profitability of DRGs, by using its practice of soliciting and using pertinent supplemental data submitted by interested parties. Specifically, we recommend that CMS obtain the kind of detailed charge and estimated cost data typically available from sophisticated cost accounting systems such as the one available from Transition Systems, Inc. If these data were submitted on a voluntary basis by groups of hospitals that have implemented these systems, CMS could study the degree of variation in the charge-to-cost ratios within departments and by DRG. CMS could use these data to refine its proposed DRG

reclassifications and/or in the associated DRG weights. The use of more detailed cost accounting information would help reduce the tendency of hospital financial experts to view as unreliable any weights that are developed on a weighted basis using Medicare cost report information at a departmental level (or on a more aggregated basis, as proposed by CMS).

We recognize that if CMS were to pursue our suggestion and seek additional, detailed charge and cost data, it would need additional time to obtain and analyze the supplemental data. Therefore, we believe that CMS should use the supplemental data, if it is acquired, to refine any weight changes that it elects to implement before such supplemental data become available.

2. Cost-Based Weights: Outlier Threshold

Currently, charges associated with outlier cases are not removed from the standardized charges that are used to calculate the relative, charge-based DRG weights used in the DRG system. Instead, an across-the-board offset adjustment is used to reduce all DRG weights to account for the targeted level of outlier payments. This approach tends to assign weights that are too high to those DRGs that have relatively high numbers of outliers, and weights that are too low to DRGs that have relatively low numbers of outliers. The fact that the same "fixed loss" threshold is used across all DRGs makes it much more likely that DRGs with high weights will generate higher proportional numbers of outliers and receive, in turn, the benefits of higher weights. These factors add to the profitability distortions that are included in the existing DRG weighting system.

We believe that CMS should use its existing authority, and seek additional authority from Congress where needed, to change its outlier policy to identify outliers on a more equitable basis across DRGs and to remove the effects of outliers from the calculation of the DRG weights. Currently, those hospitals that have higher case mix indices are likely to benefit excessively, to the detriment of other hospitals, from these weaknesses in the outlier and DRG weighting policies. The adoption of the severity-adjusted DRG system will help to address the outlier issue and the recalibration of weights and the removal of the outlier effects will further improve the fairness of the DRG system.

C. Impact of Proposed DRG Recalibrations and HSRV Weight Changes on Medicare Advantage Plans

The Medicare Advantage allowances that are paid to participating health plans reflect fee-for-service hospital payments. Accordingly, Medicare Advantage plans have to take Medicare hospital payments into account when creating their hospital networks and establishing hospital payment arrangements. Administrative efficiency considerations and the desire to offer Medicare Advantage members stable hospital networks dictate that

private health insurers such as WellPoint enter into multi-year hospital contracts for Medicare Advantage purposes. In many instances, Medicare Advantage rates at hospitals are not directly linked to the CMS hospital payment structure. Accordingly, health insurers' payments will not automatically adjust to reflect the Medicare changes. Health insurers in general have limited ability to make changes needed to keep Medicare Advantage hospital payments in line with Medicare's fee-for-service payment levels, especially if insurers have only a short lead time to react before CMS implements such changes. In addition, in those instances where insurers' Medicare Advantage hospital payments are directly linked to Medicare's payments, they can anticipate that hospitals negatively affected by the changes, such as those specializing in cardiac surgery, may seek payment adjustments from insurers to fully or partially defray those payment impacts. In some instances, these hospitals might even seek to terminate their contracts with insurers, and the insurer's ability to pay the hospital on a non-contracted basis at Medicare fee-for-service payment levels might not be sufficient to prevent network disruptions.

We believe that the potential impact of the proposed DRG changes on Medicare Advantage hospital networks is another reason for CMS to postpone the changes as suggested below.

D. Recommendations

Based on the above, we recommend that CMS do the following:

- Postpone implementation of the cost-based weights until October 1, 2007;
- Postpone implementation of severity-adjusted DRGs until October 1, 2007, and adopt a non-proprietary severity adjusted grouper available at reasonable cost from multiple vendors;
- Publish in the Federal Register, not later than October 1, 2006, CMS's best estimates, on a hospital-specific basis, of the incremental effects on Medicare payments of its contemplated changes in the DRG grouping system and the associated weights, as those changes are known or anticipated as of the date of publication of the Final Rule for fiscal year 2007. Additionally, publish in the Federal Register, to accompany the Proposed Rule for fiscal year 2008, the anticipated hospital-specific effects of any proposed severity-adjusted DRG changes for fiscal year 2008; and follow this information up in the Final Rule with updated hospital-specific impact estimates of the effects of any changes adopted in the Final Rule for fiscal year 2008.

172

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

June 12, 2006

Mark B. McClellan, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS –1488 – P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS- 1488-P — Medicare Program; Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Payment Rates; Proposed Rule (*71 Federal Register 23996)*, April 25, 2006.

Dear Administrator McClellan:

The California Hospital Association (CHA), on behalf of its nearly 500 member hospitals, health systems and ancillary providers, respectfully submits comments regarding the proposed changes to the inpatient prospective payment system (IPPS). In addition to these comments, CHA supports the comments and recommendations of the American Hospital Association (AHA).

DRG Relative Weights

In response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC) to address the proliferation of physician-owned, limited-service hospitals, the Centers for Medicare & Medicaid Services (CMS) proposed the biggest changes to the calculation of diagnosis-related group (DRG) relative weights since the creation of the prospective payment system (PPS). These changes would significantly redistribute payments among the DRGs and among hospitals. Specifically, CMS proposes the use of hospital-specific relative values (HSRVs) and a modified version of cost-based weights rather than charge-based weights in fiscal year (FY) 2007. CMS also proposes an alternative patient classification system called consolidated severity adjusted DRGs (CS-DRGs), with implementation likely in FY 2008.

While CHA supports meaningful improvements to Medicare's IPPS with hospitals standing to potentially gain or lose significant Medicare funds and questions remaining about the concepts and methodology CMS plans to use to create the changes, and about whether the changes will create a better payment system, CHA, in agreement with AHA, believes more time is needed to understand the significant proposed policy changes, which redistribute from $1.4 billion to $1.7 billion within the inpatient system. Analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payments. Moreover, the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. Moving forward requires thoughtful change.

Below are CHA's detailed comments that further explain our concerns and recommendations on the proposed DRG weight and classification system changes.

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CMS proposes an alternative to MedPAC's approach to HSRVs and cost-based weights that could be characterized as a short cut. CMS asserts that this combined methodology, known as the HSRV cost center methodology (HSRVcc), achieves similar results in a more administratively feasible manner. That is not the case. Specifically, the CMS proposal involves two major steps:

1. Develop, on a charge-basis, hospital-specific relative weights for each DRG. CMS established 10 cost center categories based on broad hospital accounting definitions: routine day costs; intensive care day costs; and eight ancillary cost centers. CMS calculated DRG relative weights for each of the 10 cost centers by DRG for each hospital and then used those hospital-specific weights for calculating national DRG weights. CMS' current process aggregates charges for all hospitals at the DRG level to calculate weights. CMS believes the new approach removes the variation introduced by hospital characteristics, such as teaching, disproportionate share, location and size, among others.

2. "Scale" the charge-based DRG weights to "costs" using the national cost center cost-to-charge ratios (CCRs) developed from the cost report data (as opposed to using hospital-specific CCRs at the claim level). CMS believes this approach will remove the effect of different CCRs across departments within hospitals. CMS chose this methodology because the use of national average rather than hospital-specific departmental CCRs is administratively easier.

CHA supports the move to cost-based weights, but believes CMS' proposed method is flawed. More work is needed to determine the best way to create cost-based weights. Hospitals are willing to work with CMS in a process to develop consensus around the right way to make this change. Below are our detailed concerns and questions regarding the proposed HSRVcc methodology.

HSRVcc METHOD CONCERNS

CHA believes that more time is needed to develop a sound methodological approach to create cost-based weights and to understand their potential impact.

1. **Errors:** While analyzing CMS' proposed rule, AHA uncovered a series of data errors, inconsistencies across databases and questionable methodological choices. Further analyses commissioned by AHA, the Association of American Medical Colleges and the Federation of American Hospitals, and conducted by The Moran Company, Inc., to investigate these questions, showed that small changes in method lead to large changes in DRG weights, signaling that the proposed changes are highly unstable.

   For instance, the following more minor inconsistencies were identified:

   - CMS inadvertently included organ acquisition costs in the data used to set weights for DRGs. These costs should be excluded. This error has a material effect on the resulting weight calculation for transplants. For example, CMS publishes a weight of 5.5466 for DRG 302 (Kidney Transplant), but with this correction, The Moran Company calculates a weight of 3.0102.

- CMS was inconsistent in its treatment of certain categories of hospitals between its calculation of the FY 2007 HSRVcc weights and the proposed CS-DRG weights, making it hard to compare the results. For example, hospitals in Maryland were included in the FY 2007 MedPAR data used for the HSRVcc weight calculation and excluded from the CS-DRG calculation.

- The Moran Company used transfer-adjusted charges prior to calculating weights. It was CMS' policy to do this. However, it is unclear whether the weights published for CS-DRGs included this step.

- Data cleaning steps used were not always consistent with standard CMS practices (e.g., removal of cases with 0 charges, low volume DRGs, etc.).

- The cleaning steps applied to the cost report data were not consistent with the cleaning steps applied to the MedPAR claims data, which resulted in different hospitals being included in data sets used for the calculation of the weights and the calculation of the scalers to the weights. For example, hospitals in Maryland and hospitals without cost reports for FY 2003 were excluded from the cost report data used to calculate the scalers and included in the MedPAR file used to calculate the weights.

2. **Trimming:** CMS trimmed the cost center CCRs at 1.96 standard deviations from the geometric mean. We believe that this skews the CCRs, as the hospitals with high routine charge mark-ups are systematically removed from the calculation. This results in the exclusion of 198 hospitals' routine CCRs, accounting for more than 26 percent of total routine charges. It also creates a mismatch between the CCRs used and the charges they are applied to, as the hospitals that are trimmed out of the CCRs are still included in the charges that are then reduced to costs to determine the cost shares.

3. **Weighting:** CMS also hospital-weighted rather than charge-weighted the calculation of the CCRs, which in turn are used to calculate the scaling factors used to convert the charge-based relative weights to "cost." There are several issues with this approach:

   - This approach gives an equal weight to each hospital in the national cost-to-charge ratio calculation even though hospitals can range in size from fewer than 25 to more than 1,000 beds.
   - This method is inconsistent with the method of averaging used to develop the cost center-specific DRG weights to which the scaling factors are applied. For this part of the analysis, CMS calculated hospital-specific DRG relative weights, but then used a case-weighted average to develop the national value.
   - The hospital-weighted approach results in a 1 percent to 54 percent difference versus a charge-weighted approach in the resulting scaling factors used for the conversion to cost.

The above errors in the calculations over-weight CMS' routine cost shares and under-weight the ancillary cost shares, creating erroneously large swings in DRG weights. Table 1 illustrates how these methodological problems affect the factors used to scale the cost center-specific relative weights. This table shows the impact of trimming the cost center CCRs at 3.0 rather than 1.96 standard deviations from the geometric mean and charge weighting rather than hospital weighting the calculation of the national average CCRs that are used in developing the scalers.

Table 1

Impact of Methodological Changes on "Scalers"

Published versus Revised with Methodological Changes

Scaler	CMS Published	Methodological Changes			Percent Change vs. Published
		Trimming Only	Weighting Only	Weighting/ Trimming	
Routine days	0.2881	0.2882	0.2646	0.2490	-14%
Intensive days	0.1919	0.1933	0.1668	0.1636	-15%
Drugs	0.0877	0.0884	0.0939	0.0970	11%
Supplies	0.1150	0.1142	0.1325	0.1383	20%
Therapeutic	0.0384	0.0381	0.0390	0.0388	1%
Operating room	0.0812	0.0838	0.0861	0.0888	9%
Cardiology	0.0241	0.0246	0.0351	0.0371	54%
Laboratory	0.0670	0.0659	0.0681	0.0687	3%
Radiology	0.0427	0.0437	0.0460	0.0474	11%
Other services	0.0639	0.0600	0.0677	0.0712	12%

Source: Moran Company analysis.

These methodological problems have a large impact on the relative weight calculations at the DRG level. Table 2 shows, for key DRGs, how these methodological problems affect the DRG weights and, therefore, hospital payments.

Table 2
DRG Weights with Current Methodology vs. HSRVcc with Various Corrections
High Volume DRGs with Largest Changes in Weights Due to Corrections

				New DRG Weights: Published vs. Corrected			Change vs. Old Weights		
DRG (v24)	DRG Title	Number of discharges	Current Charged-based Weights w/v24 Grouper	CMS Published HSRVcc Weight	HSRVcc w/ Technical Corrections Only	Corrected, Weighted and Trimmed CCRs	DRG Weight Change Current Method vs. Published	DRG Weight Change Current vs. Corrected, Weighted, and Trimmed	Published vs. Corrected, Weighted, and Trimmed
430	PSYCHOSES	74,671	0.6561	1.2316	1.2416	1.1110	87.7%	69.3%	-9.8%
12	DEGENERATIVE NERVOUS SYSTEM DISORDERS	56,042	0.8983	1.0105	1.0099	0.9635	12.5%	7.3%	-4.7%
475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	119,513	3.4630	3.8279	3.8386	3.6573	10.5%	5.6%	-4.6%
277	CELLULITIS AGE >17 W CC	118,691	0.8676	1.0015	1.0026	0.9578	15.4%	10.4%	-4.4%
87	PULMONARY EDEMA & RESPIRATORY FAILURE	96,506	1.3854	1.5310	1.5324	1.4699	10.5%	6.1%	-4.0%
320	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W CC	224,491	0.8611	0.9538	0.9544	0.9162	10.8%	6.4%	-3.9%
294	DIABETES AGE >35	97,122	0.7750	0.8642	0.8636	0.8307	11.5%	7.2%	-3.9%
296	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W CC	246,948	0.8213	0.9041	0.9042	0.8701	10.1%	5.9%	-3.8%
79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	159,894	1.5939	1.7331	1.7359	1.6680	8.7%	4.6%	-3.8%
243	MEDICAL BACK PROBLEMS	100,498	0.7888	0.8680	0.8693	0.8363	10.0%	6.0%	-3.7%
564	OTHER VASCULAR PROCEDURES W CC W/O MAJOR CV DX	77,003	2.0890	1.9483	1.9560	2.0085	-5.7%	-3.9%	3.1%
110	MAJOR CARDIOVASCULAR PROCEDURES W CC	57,436	3.8616	3.6419	3.6558	3.7563	-5.7%	-2.7%	3.1%
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG	119,991	1.4508	1.1870	1.1732	1.2380	-19.6%	-14.7%	6.1%
544	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY	444,118	1.9514	1.8941	1.9047	2.0147	-2.9%	3.2%	6.4%
551	PERMANENT CARDIAC PACEMAKER IMPL W MAJ CV DX OR AICD LEAD OR GNRTR	53,717	3.0991	2.6339	2.6491	2.8453	-13.3%	-6.4%	8.0%
552	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT W/O MAJOR CV DX	81,744	2.0837	1.7670	1.7771	1.9468	-15.2%	-6.6%	10.2%
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG	91,648	1.1117	0.7892	0.7913	0.8717	-29.3%	-21.6%	10.9%
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX	123,550	2.8755	2.1323	2.1499	2.4236	-25.8%	-15.7%	13.7%
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	58,009	5.2591	4.1471	4.1795	4.7999	-21.1%	-8.7%	15.7%
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	191,677	2.1920	1.4299	1.4456	1.7238	-34.8%	-21.4%	20.6%

Source: Moran Company analysis of FY 2007 proposed inpatient PPS rule. Uses FY 2005 MedPAR.
Notes: High volume DRGs defined as over 50,000 cases. Those included in the table were those with the greatest absolute change in weight moving from the CMS published DRG weight to the DRG weight calculated by trimming CCRs at 3.0 standard deviations, using weighted CCRs, and correcting for technical errors.

These changes have a material impact on hospital payments. CMS' method for weighting and trimming redistributes $1.4 billion among hospitals. Charge weighting the CCRs and trimming them at three standard deviations would reduce the shift in dollars to $900 million, a reduction of half a billion dollars, or 33 percent. This highlights the need for more work to validate each methodological step to understand how it affects payment and ensure it adds to "accuracy."

4. **Failure to Calculate Costs at the Claim Level:** CMS chose to use charges to initially calculate the relative weights at the DRG level and then a national scaler to make the conversion to "cost-based" weights. The national scaler converts the 10 cost center charge-based weights to one national weight using the actual share of costs across departments. CMS maintains that this adjusts for differential mark-ups across hospital departments. In contrast, MedPAC estimated *costs* at the claim level to calculate relative weights. CMS provided no validation of the methodological shortcut it proposes.

5. **Cost Centers:** CMS aggregates charges into 10 cost centers for each DRG, then applies a cost-center level CCR (derived from the cost reports) to charge figures (from claims data). However, because hospitals often report charges on the cost reports differently than charges on the claims, the cost-center level CCRs are calculated based on a different set of charges than the charges to which the CCRs are later applied. We believe this may materially distort the DRG weights and needs to be thoughtfully considered and accounted for in any methodology. If CMS is going to move to cost-based weights, regardless of the methodology, hospitals will need time to align their mapping of cost centers into departments or cost categories for purposes of cost reporting with that of claims reporting.

6. **Validation:** As mentioned above, CMS provided no analysis to validate that the proposed changes result in better payment policy. While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone indicates the need for further analysis and study. CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the result, including:
    - Compare CMS weights to MedPAC's HSRV-cost approach;
    - Compare CMS weights to an approach using standardized costs (as opposed to HSRV);
    - Compare CMS weights to weights calculated by estimating costs at the claims level using the 10 cost center approach;
    - Evaluate alternative methodologies for estimating costs (e.g., method used by New York state's Medicaid program);
    - Compare stability of weights over time; and
    - Determine whether payment policy is improved.

Assessment of "payment accuracy" conducted by The Moran Company, as well as The Health Economics and Outcomes Research Institute (THEORI), a division of the Greater New York Hospital Association, finds the CMS HSRVcc approach to be not marginally better than the current system. Fixing the major methodological flaws yields minimal improvement, according to THEORI. CMS' HSRVcc approach actually creates new areas of care where systematic incentives for specialization could occur. This analysis raises significant questions about CMS' approach and further analysis should be conducted before any changes to the current charge-based methodology are made. These analyses will help determine the most effective and administratively feasible approach for a shift to cost-based weights in FY 2008.

New Patient Classifications: Severity of Illness

CMS also proposes moving to an entirely new patient classification system beginning in FY 2008 *or earlier*. Currently, Medicare uses 526 DRGs to classify all Medicare patients. CMS considered use of 3M's all patient refined DRGs (APR-DRGs) as an alternative to its current DRGs, which would increase the number of categories to 1,258. However, CMS ultimately proposed refining the APR-DRG system by consolidating APR-DRGs into fewer categories. This would result in a new DRG system with 861 consolidated severity-adjusted DRGs, or CS-DRGs.

CHA believes that the need for and best approach to changing the patient classification system has not been concretely and objectively demonstrated. Analysis that is more careful is needed, along with greater access to the specifics of CMS' methodology and the new GROUPER. Below are our detailed concerns and questions about this proposal.

CS-DRG METHOD CONCERNS

1. **Validation:** It is unclear whether there is a need for a new patient classification system. More work is needed to assess the proposed system and others that might be considered. As with the HSRVcc proposal, CMS provided no analysis that shows that the proposed changes result in an improved hospital payment system compared to the existing DRG system or APR-DRGs.

   CMS must test the degree to which the variation in costs within cases at the DRG level is reduced under both CS-DRGs and APR-DRGs. Payment classifications that still exhibit a high degree of cost variation should be identified and potentially revised. We suggest comparing the distribution of the coefficient of variation at the DRG level for various grouping approaches.

   For instance, CMS chooses to collapse the tier-four cases within major diagnostic categories (MDCs). It is unclear whether all of the tier-four cases are clinically cohesive enough to be combined and whether consolidation adequately considers variations in resource requirements. CMS also aggressively collapses the DRGs with low Medicare volume, such as obstetrics, psychiatric and substance-use services without any discussion of the private sector that often bases payment off the Medicare inpatient DRG system. CMS believes that a new patient classification system that distinguishes more-sick from less-sick patients will reduce the "cherry picking" of healthy patients, but there may be other, easier ways to accomplish this. For example, CMS embarked on a new way to differentiate patients last year based on the absence or existence of a major cardiovascular diagnosis but did not discuss the possibility of other similar, less disruptive changes to the system as an option in this year's rule.

   Even more fundamentally, today's DRG system was created to distinguish the resource use required among patients. Over time, the DRG system has been modified to reflect changes in clinical practice and technology. The APR-DRG system is based on severity of illness, not necessarily the resource use required. The impact of a move to CS-DRGs – an APR-DRG hybrid – is unclear. However, the implications of moving from a resource-based system to a severity-based payment system must be more fully explored and understood.

2. **Budget Neutrality Adjustment:** CMS suggests in the proposed rule that it would reduce payments to hospitals by instituting a budget neutrality adjustment to offset the fact that case mix may increase because of improved coding rather than actual changes in acuity. However, CMS did not propose an adjustment or even a methodology for determining an adjustment. CMS often institutes such adjustments that are based on assumptions but never checked or later corrected. We recommend that CMS hold off on such an adjustment until there is evidence that one is needed.

3. **Availability of the GROUPER:** The proprietary nature of the proposed CS-DRG GROUPER is of concern. The current DRG GROUPER logic has been in the public domain since the inception of the PPS. Without the new GROUPER logic, it is virtually impossible for CHA or anyone else to thoroughly analyze the system and comment – without access to the new GROUPER, we have no understanding of how and why patients fall into certain CS-DRGs and cannot evaluate whether it represents policy improvement. If CS-DRGs are adopted and the GROUPER remains proprietary, CHA would be limited in its ability to educate and assist our member hospitals. Moreover, a single company's monopoly would be both more expensive and more difficult to integrate into our hospitals' existing systems. We urge CMS to make any new classification system widely available to the public.

4. **Too Few Diagnoses and Procedures Considered: CHA is** concerned that CMS' GROUPER does not use all diagnoses and procedures that affect a patient's severity of illness and/or the resources utilized. The current DRG GROUPER only considers nine diagnoses and up to six procedures. Hospitals submit claims to CMS in an electronic format. The HIPAA compliant electronic transaction 837i standard allows up to 25 diagnoses and 25 procedures. Many fiscal intermediaries are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the GROUPER to assign a DRG.

   Capturing all diagnoses and procedures meeting the definitions of reportable secondary diagnoses and procedures will provide a more complete picture of patient complexity. As CMS considers methodologies for refining the patient classification system, the number of secondary diagnoses may be an important factor in determining differences in patient characteristics. This is particularly true of patients with many chronic illnesses that add to the complexity of treating them.

Specifically, CHA supports the following:

- **One-year Delay:** CHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. The AHA and the hospital field are committed to working with CMS over the next year to address these concerns.

- **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

- **A New Classification System Only if the Need Can Be Demonstrated:** CHA does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

- **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

- **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.

- **Collaborative Approach to Moving Forward**: CHA, in coordination with the AHA, commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

Changes to DRG Classifications and Coding
For FY 2007, CMS proposes few changes to the DRG classification system. Specific proposed changes to DRG classifications are summarized below.

DRGs: Pancreas Transplant.
CHA agrees with the proposed coding changes for DRG 513 (Pancreas Transplant), which removes the requirement that pancreas transplant patients also have kidney disease. This change is consistent with the newly approved National Coverage Determination (NCD) to cover pancreas transplants alone as reasonable and necessary under limited circumstances for patients with Type I diabetes.

DRGs: Dual Array Implantable Neurostimulators for Deep Brain Stimulation.
CHA opposes CMS' recommendation to keep the implantation of dual array implantable neurostimulators for deep brain stimulation in DRG 1 (Craniotomy Age >17 with CC) and DRG 2 (Craniotomy Age >17 without CC). CMS should recognize the higher resources associated with this technology.

DRGs: Carotid Artery Stents.
CHA opposes the proposed delay in making any changes to carotid artery stent cases. The higher costs associated with carotid stents should be recognized within the existing DRG system.

DRGs: Cardiac Resynchronization Therapy, Defibrillators (CRT-D). We agree with the proposal to add code 37.74 (Insertion or Replacement of Epicardial Lead [Electrode] into Atrium) to the DRG logic, so that all types of defibrillator devices and lead combinations would be included in the following DRGs:

- DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheter);

- DRG 535 (Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock); and

- DRG 536 (Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock).

This change would bring the DRGs into alignment with the change in coding advice to assign code 37.74 in conjunction with implantation of CRT-D defibrillators.

Application of Major Cardiovascular Diagnoses (MCVs) List to Defibrillator DRGs. We oppose the proposal to delay refining defibrillator DRGs based on MCVs. We believe it is appropriate for CMS to apply a clinical severity concept similar to the approach used in FY 2006 to refine cardiac DRGs to an expanded set of DRGs (e.g., defibrillator DRGs) based on the presence or absence of an MCV.

DRGs: Hip and Knee Replacements. For FY 2006, new codes were created to differentiate between new and revised hip and knee replacements. In addition, codes that are more specific were created to identify the joint components replaced. After publication of the FY 2006 inpatient PPS final rule, a number of commenters advised CMS that the DRG logic for DRG 471 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) included knee and hip procedures that are not bilateral or do not involve multiple major joints. We agree with CMS' proposal to remove the codes from DRG 471 that do not capture bilateral and multiple joint revisions or replacements.

DRGs: Severe Sepsis. We agree that providers have found the coding of systemic inflammatory response syndrome (SIRS), sepsis and severe sepsis confusing in the last few years. The classification of these conditions has changed several times during this period. We concur that data have not been consistent and that a new DRG for severe sepsis would be inappropriate. However, we recommend that a change be made so patients with severe sepsis associated with respiratory failure requiring mechanical ventilation may be properly recognized. The ICD-9-CM classification instructions require that these patients be coded with the systemic infection as the principal diagnosis. The infection codes do not group to DRG 475 (Respiratory System Diagnosis with Ventilator Support) despite the use of resource-intensive mechanical ventilation (procedure code 96.7). This results in a significant loss of reimbursement for these patients.

Since the change in coding sequencing of these patients, the Coding Clinic Editorial Advisory Board has discussed this issue several times. In addition, several proposals have been submitted to the ICD-9-CM Coordination and Maintenance Committee to allow the sequencing of respiratory failure as the principal diagnosis. To date, no changes have been made. At this point, reverting the sequencing instructions would be confusing to coders and would once again disrupt trend data.

CHA agrees with AHA's recommendation regarding considering mechanical ventilation as a pre-MDC DRG based on the procedure code. If this is not possible, we recommend that CMS add systemic infections (038.xx,) as acceptable principal diagnoses for DRG 475 when reported in conjunction with mechanical ventilation or tracheostomy.

Outliers

In the rule, CMS proposes establishing a fixed-loss cost outlier threshold equal to the DRG prospective payment rate, plus any add-on payments for new technology, disproportionate-share hospital (DSH) payments, and any indirect medical education (IME) payments, plus $25,530 for FY 2007. The current threshold is $23,600. Even though 5.1 percent was allocated in setting the

FY 2005 and FY 2006 rates, CMS estimates that it spent 4.1 percent of total payments in outliers in FY 2005 and will spend 4.7 percent in FY 2006.

As we have expressed in previous comment letters, CHA remains concerned that the increase in the threshold is unwarranted. According to our analyses, actual outlier payments for FY 2006 are estimated to be 0.47 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments. CMS spent only 3.8 percent or $1.15 billion less than set aside in FY 2005, and only 3.5 percent, or $1.3 billion less than the funds withheld in 2004.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2004, in combination with the first quarter of 2005, to the last quarter of 2005, in combination with the first quarter of 2006, to establish an average rate of increase in charges. This results in a 7.57 percent rate of change over one year, or 15.15 percent over two years.

While we appreciate that CMS is proposing this methodology in an effort to avoid using data from 2003 when charges may have been atypically high, CHA opposes using the proposed charge inflation methodology as it will only result in an inappropriately high outlier threshold and a real payment cut to hospitals.

AHA conducted a series of analyses to identify a more appropriate methodology. Below we put forth for CMS' consideration a methodology that incorporates both *cost* inflation and *charge* inflation. CHA agrees with AHA's assessment that the use of more than one indicator will make the threshold calculation more accurate and reliable. AHA's methodology is outlined below:

First, AHA inflated 2005 charges by 15.71 percent (the inflation factor used by CMS in the proposed rule) and then reduced the charges to costs. Instead of using the cost-to-charge ratios (CCRs) from the CMS Impact File, we used the CCRs from the March 31, 2006, HCRIS release. In addition, we accounted for the nine-month lag from the end of a cost-reporting period until the FI is able to update the CCR. AHA accomplished this by projecting forward from the most recent fiscal period in the March 31 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining federal FY 2007 outlier payments.

The cost inflation factor for projecting CCRs was determined from the cost reports of a cohort of 3,253 matched hospitals for periods beginning in federal FYs 2002, 2003 and 2004. All three cost reports were available for each hospital from the recent update of HCRIS. The 2002-2004 aggregate annual rate of increase in the cost per discharge for these hospitals was 5.69 percent[1]. This cost inflation factor and the CMS charge inflation factor of 7.57 percent were used to project CCRs over the time periods described above. The projected CCRs were applied to projected federal FY 2006 charges to simulate the determination of costs for FY 2007 outlier payments.

[1] An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 2,729 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2006 HCRIS update.

The estimated fixed-loss amount that would result in 5.1 percent outlier payments under this methodology is $24,000.

CHA strongly urges CMS to adopt this methodology, which is applicable regardless of what DRG changes are made or not made in FY 2007. Based on our analysis, we estimate that the fixed-loss threshold necessary to achieve 5.1 percent in FY 2006 should have been set at $21,275 as compared to the $23,600 actually utilized. We believe CMS underspent the funds set aside for outliers by an estimated $3 billion over FYs 2004, 2005 and 2006. CHA urges CMS to adopt our recommended methodology to lower the outlier

threshold, to do otherwise results in a real cut in payments to hospitals that cannot be recouped. If CMS leaves the threshold at $25,530, rather than dropping it to $24,000, we believe that CMS will again significantly underspend by over $300 million. Attached is the full analysis, conducted by Vaida Health Data Consulting.

Quality Reporting

The Deficit Reduction Act of 2005 (DRA) expands quality-reporting requirements for hospitals to be eligible to receive a full market basket update. To be eligible for a full market basket update in FY 2007, CMS proposes using hospitals' data submissions for the first three calendar quarters of 2005 for the existing 10 quality measures. CMS also proposes requiring hospitals to pledge to submit the full set of 21 quality measures for services retroactively, beginning in *CY 2006* to remain eligible. Hospitals must continually submit quarterly information on the quality measures and pass the validation process established for FY 2006 to be considered a reporting hospital. Hospitals failing to submit data for the first calendar quarter of 2006 by August 15 would receive an inpatient update equal to the market basket minus two percentage points. Hospitals that fail data validation tests for data submitted for the first three calendar quarters of 2005 would also lose the two percentage points from the market basket update.

CHA fully supports CMS'and HQA's effort to make more information on hospital quality available to the public. CMS proposal, however, would require hospitals to reopen files from which data have already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door for the introduction of many new kinds of errors in the data. To require this reopening of the files makes no sense. CMS should make the data collection prospective. This could be accomplished by requiring that hospitals that want a full market basket update pledge to submit the relevant data for all 21 measures for patients beginning on or after July 1.

The DRA gave the Secretary of the Department of Health and Human Services (HHS) the authority to expand the number of measures that must be reported to qualify for full market basket update in future years. We urge CMS to select measures only from those used by HQA for public reporting. To choose different measures would thwart efforts to streamline quality reporting, add to and dilute efforts to create a single source to share solid reliable information with the public. In addition, CHA recommends that CMS consider publishing all proposals to expand the set of measures linked to payment at least one full year prior to the start of the fiscal year. This will

enable hospitals and their vendors to put the needed data collection processes in place to be able to provide the requested data.

Further, CHA agrees with CMS that it is critical that the collected data be validated. The process used to validate the HQA data was reviewed by the Government Accountability Office, which concluded that there was "a high overall baseline of accuracy," but recommended several changes to improve the validation process. CMS proposes to look at the validation results for data submitted on patients who were discharged during the first three calendar quarters of 2005. CMS has hired a contractor to randomly select five patient records per quarter. That contractor selects the patients, asks the hospital to send a copy of the medical record for the hospitalization of the patients that occurred during that period, and then re-abstracts the same data that the hospital abstracted from the medical record. A comparison is made between the data the hospital submitted and the data the contractor abstracted, and if there is at least an 80 percent agreement, the hospital is said to have passed validation. In the proposed rule, the hospital would have to have at least 80 percent agreement across the 15 medical records that the contractor re-abstracted. This methodology assumes that the contractor has correctly re-abstracted the data and that discrepancies must mean erroneous data submission on the part of the hospital. However, that is not always the case. This validation process is still in its infancy and seems to be working to correctly validate the information submitted by many, but unfortunately not all, hospitals.

It is our understanding that CMS is aware of the problems with the validation process and that it has begun to work to improve the process reliability so it can be used to support payment decisions. Now, we believe that the problems with the validation process itself need to be resolved before any payment decisions are made solely based on the contractor's work. CHA urges CMS to review, on a case-by-case basis, any incidence where a hospital's payment would be put in jeopardy because of the validation process. CMS should allow the hospital to submit information showing that it made a good-faith effort to supply the data warehouse with accurate information so that the public could be informed about the quality of its care. If the hospital has made a good-faith effort, it should receive full payment regardless of whether the data are deemed accurate enough for public display. In addition, CMS should instruct its QIO data warehouse to accept any significant corrections so that the public can have a full and accurate picture of hospital quality.

Hospital Wage Index

Occupational Mix Adjustment to Proposed FY 2007 Index

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 requires CMS to collect data every three years on the occupational mix of employees from hospitals subject to the IPPS in order to construct an occupational mix adjustment to the wage index to control for the effect of hospitals' employment choices — such as greater use of registered nurses (RNs) versus licensed practical nurses or certified nurse aides — rather than geographic differences in the costs of labor.

In the proposed rule, CMS initially stated that it would again limit the occupational mix adjustment to 10 percent because of concerns regarding the validity of the data and the potential financial impact on hospitals. However, because of the decision handed down by the U.S. Court of Appeals for the Second Circuit on April 3 in *Bellevue Hospital Center v. Leavitt*, CMS on May 12 released a proposed rule revising the occupational mix adjustment portion of the FY 2007 IPPS proposed rule. Under the court ruling, CMS must collect new data on the occupational mix of hospital employees and fully adjust the area wage index (AWI) for FY 2007.

Hospitals are required to collect the hours and wages for employees from January 1 through June 30, 2006. Data initially was supposed to be collected by July 31; however, hospitals are required to submit data by June 1 for the first calendar quarter of the year and by August 31 for the second calendar quarter. Data from the first quarter will be used to adjust the FY 2007 AWI, while data for the full six months will be used to adjust the AWI for FYs 2008 and 2009.

Definitions and Covered Employees. With respect to the interim survey, members voiced concern regarding the placement of certain employees. Examples include surgical technicians, paramedics who are employed by the hospital and usually work in the emergency department, and unit secretaries who are also known as ward clerks. CMS clarified after the proposed rule was released that these employees should be placed in the "all other" category for the interim-collection. For future surveys, we recommend that CMS re-evaluate where these employees belong. We caution however that such changes should not be made to the ongoing collection, as it would necessitate the resubmission of the first calendar quarter's data to ensure that both quarters could be used for FYs 2008 and 2009. If CMS believes that such changes are warranted, then the hospitals will need notification prior to the release of the final IPPS rule in order to meet the August 31 deadline for submissions.

Cost Centers. We agree with CMS' "bright line" clarification for this collection that only nursing personnel within the cost centers listed should be included in that category for the purposes of consistency. It is significantly less work for hospitals to focus on certain cost centers, and we continue to support this methodology. We believe that the vast majority of nursing personnel within a hospital fall within these cost centers and do not believe that CMS should include every cost center that may have a few nursing personnel included in it.

However, CMS should consider refining the list for future collections. Every hospital has a different method for attributing costs to the cost centers, thus there are probably a few cost centers that contain a significant number of nursing personnel for certain hospitals that were not captured for this collection. Given the shortened comment period in combination with the magnitude of the other changes proposed by CMS in the IPPS rule this year, we were unable to extensively research which cost centers CMS should add. We suggest that CMS accept comments on any potential changes to the cost center list before making such changes. In addition, we believe that additional cost centers should *not* be added to the ongoing collection, as it would necessitate the resubmission on the first calendar quarter's data to ensure that both quarters could be used for FYs 2008 and 2009. If CMS believes that such changes are necessary for the current collection, then hospitals would need notification prior to the release of the final IPPS rule in order to meet the August 31 deadline for submissions.

Non-responsive Hospitals. Because data from all hospitals is needed to construct an accurate national average hourly wage, full participation is critical. There is a general sentiment that hospitals that do not participate should not benefit from the participation of others. However, given the rushed collection and general confusion around the interim-collection, we believe that, to the extent possible, CMS should substitute data from the previous survey for hospitals that did not turn in their data for the first calendar quarter of 2006.

However, hospitals will have plenty of notice and time to submit data for the second calendar quarter in August. Thus, moving forward CMS should consider a methodology that penalizes hospitals that do not participate. We caution CMS not to simply substitute unfavorable data for these hospitals, as it also will affect other area hospitals that conscientiously reported data. CMS could alternatively substitute the national average hourly wage for non-responsive hospitals in calculating an area's wage index, and then require hospitals that did not turn in data to use something lower than their area's wage index. This would avoid CMS having to create an extensive hospital-specific wage index table and would minimize the effects on the other hospitals in the area. CHA recommends that CMS to construct an application of the occupational mix adjustment that encourages hospitals to report but does not unfairly penalize neighboring hospitals.

Corrections. Again, as this collection has been rushed, the idea is to allow hospitals to improve the data for the FYs 2008 and 2009 adjustment. For hospitals that were previously non-responsive, the submission of the first calendar quarter would remove any penalty, while those that continue to be non-responsive will continue to incur a penalty. CHA urges CMS to allow hospitals to turn in both calendar quarters of data in August whether for the first time or with corrections.

Comment Timeframe. While we understand, the time constraints that CMS is working under, CHA is concerned that the 30-day comment period was does not provide hospitals with sufficient time to comment. In addition, we believe it would be appropriate for CMS to take comments on the calculation after the initial results of the survey are tabulated and posted. The results of the survey could be material. For instance, if the segregation of RNs who are management versus RNs who are staff does not produce a reliable result, CMS might consider consolidating the two for the purposes of the calculation. While CMS might not have time to make such changes for FY 2007, it could entertain comments on the implementation for FYs 2008 and 2009. In light of these comments, CHA recommends that CMS publish the occupational mix adjustment changes as an interim-final rule in August with an associated comment period.

Finally, while we cannot precisely model the impact of this adjustment on our hospitals, we are extremely concerned that our California hospitals will be disproportionately harmed by this change because we are the only state in the country with state-mandated nurse-to-patient staffing ratios. We believe that this system is designed to benefit parts of the country that make greater use of lesser-skilled nurses and allied health professionals, and to reduce payments in areas that make greater use of registered nurses in nursing positions. Because of California's nurse staffing laws, which specifically mandate Registered Nurse (R.N.) staff-to-patient ratios, this adjustment

will likely be especially damaging to California hospitals by reducing the payments they receive for the care they provide to Medicare beneficiaries.

Rural Hospitals

Payment Adjustments for Low-Volume Hospitals
Section 406 of the MMA provided for low-volume payment adjustment for hospitals located more than 25 road miles from another hospital that has fewer than 800 total inpatient discharges during the fiscal year, including Medicare and non-Medicare patients. The law further specifies that the payment adjustment may not be greater than 25 percent based on a formula developed by CMS that takes into account the standardized cost per case, the number of hospital discharges and the incremental costs for these discharges. CMS proposes to maintain a 25 percent increase in payments to hospitals with fewer than 200 discharges. For those hospitals with 200 to 800 discharges, CMS would not provide an adjustment. In the proposed rule, CMS noted that only two hospitals in the country would qualify under these criteria for FY 2007.

CHA is concerned that CMS chooses to ignore congressional intent by continuing to deny hospitals with greater than 200 but less than 800 discharges access to this necessary payment adjustment. In California, hospitals that have between 200 and 800 discharges continue to operate with negative operating margins, thus this adjustment is crucial to their financial health. The law gives CMS the authority to provide a low-volume adjustment for hospitals with fewer than 800 discharges. CHA urges CMS to take advantage of this authority and, to the full extent of the law and its authority, to extend the adjustment up to 800 discharges.

Medicare Dependent Hospitals and Sole Community Hospitals
The proposed rule would require an approved MDH or sole community hospital (SCH) to notify the appropriate CMS Regional Office of any change that would affect its classification as such. To date, it has been the FIs responsibility to evaluate hospitals' continuing qualification for MDH or SCH status. CMS proposes this change because of situations in which providers continued as MDHs or SCHs even though they no longer met the requirements. Thus, CMS expects the hospital to self-disclose any material changes in circumstances or potentially face a retroactive cancellation of their designation once an FI discovers its ineligibility.

CHA is concerned that if implemented, this provision will make MDHs or SCHs responsible for duties that should be performed by the FI. FIs are equipped and trained to evaluate hospitals' continuing qualification for MDH or SCH status. Requiring hospitals to monitor whether they continue to meet these requirements would impose a tremendous and unreasonable administrative burden on hospitals. If CMS requires hospitals to report changes in circumstances, then the specific types of situations should be noted and should only include aspects of their operation that are within their control (e.g., number of beds). CHA is opposed to this provision. We recommend that this function remain a responsibility of the FIs.

CMS' proposal to retroactively withdraw SCH or MDH status if a hospital does not appropriately self-report a change in circumstances could be financially devastating. Given the financial implications of disqualification, CHA believes that the proposed 30-day timetable is an insuffi-

cient amount of time for a hospital to plan for such an outcome. CHA offers the following recommendations:

- CMS should re-evaluate the proposed timetable for canceling SCH/MDH status when a hospital is found to be disqualified or self-reports disqualification and consider revoking the hospitals' status as of the following cost-reporting period.
- CMS should at minimum give consideration to whether the hospital had knowledge of the disqualifying circumstance.
- CMS should develop a prospective process for withdrawing the hospitals' SCH or MDH status. Hospitals should not have to repay CMS based on the difference between the inpatient PPS or outpatient PPS payment and the SCH or MDH payment when they did not know that they no longer qualified for the program.

MDH/SCH Volume Decrease Adjustment

In addition, an MDH or SCH may apply for special payments if it experiences a decrease that was out of its control of five or more percent in its total number of inpatient discharges from one cost-reporting period to another. If the hospital qualifies, it must demonstrate that it took measures to scale back its nursing force commensurately. The adjustment is intended to cover the fixed costs that the hospital is unable to reduce in the year following the volume decrease. CMS believes that only "core staff and services" should be covered by these special payments.

To date, CMS has used AHA's Hospital Administrative Statistics (HAS) Monitrend Data Books to compare the hospital's staffing to other similar hospitals in the area to determine if the hospital is staffing its routine and intensive care units appropriately. However, the HAS Monitrend data has not been updated since 1989, and the AHA annual survey does not provide sufficient staffing detail for this purpose. Thus, CMS proposes using the occupational mix adjustment data currently being collected for wage index purposes to calculate nursing hours per inpatient day for the hospital in question and local peer hospitals.

CHA recommends that CMS use the AHA annual survey data. Given that the occupational mix adjustment was only partially implemented in its first three years, primarily due to the questionable data and results and that the current collection may result in questionable data, we believe the AHA data should be sufficient for CMS to determine the nursing levels per patient day.

LTCH-DRG Reclassifications and Relative Weights

In the proposed rule, CMS estimates that updates to the long-term care hospital DRG (LTCH-DRG) relative weights for FY 2007, would reduce aggregate LTCH payments by 1.4 percent since re-weighting under the LTCH PPS need not be budget neutral.

CHA is concerned that the projected payment cut resulting from the re-weighting in combination with the 7.1 percent payment cut resulting from the recent LTCH PPS final rule for 2007 will cause substantial volatility for LTCH providers, and ultimately restrict access for patients needing long-term acute care services. It would be extremely difficult for any provider group to withstand an 8.5 percent cut in one year. By pursuing these changes, CMS is misinterpreting MedPAC's estimate of 2006 Medicare margins for LTCHs and creating an extremely unstable regulatory environment for LTCHs. MedPAC projected a 7.8 percent Medicare margin for

LTCHs in 2006 and recommended no market basket update for FY 2007. It should be pointed out however, that MedPAC's projection does not include the impact of the "25% Rule" limiting payments to co-located LTCHs and the new reductions associated with the LTCH short-stay outlier policy, two major policy changes that also decrease Medicare margins for LTCHs. Therefore, CMS goes too far with this proposal to reduce Medicare payments even further. It is irrational to treat the LTCH PPS differently than other Medicare payment systems by failing to re-weight the LTCH PPS in a budget-neutral manner.

Given these considerations, CHA requests that CMS rescind the proposed 1.4 percent cut and instead implement the re-weighting in a budget-neutral manner. Re-weighting in a budget-neutral manner would appropriately redistribute allocated funds among the payment categories to reflect current costs and omit the inappropriate modification of total payments due to unrelated considerations.

At this time, CMS should focus on developing further patient and facility criteria for LTCHs to ensure that clinically suitable patients continue to have access to the LTCH setting. We strongly support CMS' pursuit of a scientific foundation for these expanded criteria and are eager to review the recommendations currently under development by CMS' contractor the Research Triangle Institute.

Emergency Medical Treatment and Active Labor Act (EMTALA)
In the rule, CMS proposed making one clarification and one change to the EMTALA regulations because of recommendations made by the EMTALA technical advisory group.

First, CMS proposes altering the regulations to allow a qualified medical person other than a physician to certify false labor if it is within his or her scope of practice according to medical staff bylaws and state law. Specifically, CMS proposed to modify the definition of "labor" at 42 CFR 489.24(b) to allow a certified nurse-midwife or other qualified medical personnel operating under their scope of practice, as defined in hospital medical staff bylaws and in state law, to certify that a woman is in false labor. Not only does this change recognize that licensure and scope of practice should remain under the purview of state law and regulation it also provides hospitals with the staffing flexibility needed to maintain access to and the efficiency of vital obstetrical services, particularly in hospitals located in areas of the country that may find it difficult to attract and retain physicians, such as rural areas. CHA supports this proposal.

Second, in the proposed rule, CMS clarified that hospitals with specialized capabilities must accept appropriate transfers under EMTALA, even if they do not have an emergency department, so long as they have the capacity to treat the patient. While CHA agrees that a physician-owned, limited-service hospital should be treated as a hospital "with specialized capability or facilities" under EMTALA without regard to whether it has an ED, CHA believes additional guidance is still needed on the definition of specialized capability.

In addition, this policy does not address the problem of patients at physician-owned, limited service hospitals who suffer from complications appearing in a hospital ED with no warning call, no medical history, no operative report, no information on the anesthesia used and, often, no ability

to reach the treating surgeon for consultation. Physician-owned, limited-service hospitals should be required to have agreements with the community hospitals they plan to rely on in the event that they do not have the capacity to treat a particular patient.

CHA offers the following recommendations:

- A physician-owned, limited-service hospital should be required to have a pre-existing agreement with the community hospital(s) it intends to rely on for emergency back-up services.

- The Secretary should establish the terms that must be addressed by an agreement, including:

    - Procedures for an appropriate transfer for patients not covered under EMTALA (e.g., inpatient or outpatient whose condition develops into an emergency beyond the capability of the limited-service hospital and consequently needs to be transferred to a full-service hospital);
    - Continuity of care (e.g., telephone consultation with the receiving hospital and physician, sending the patient's medical records along when transferred, etc.); and
    - Support for maintaining full-time emergency capacity at the community hospital, including on-call coverage (e.g., physician-owned, limited-service hospital physicians serve in on-call panels at the community hospital, or the physician-owned, limited-service hospital provides financial support to the community hospital to maintain on-call coverage).

Add-on Payments for New Services and Technologies

In the proposed rule, CMS proposes retaining two of the three existing approved technologies for add-on payments and is considering three additional technologies.

In order for a new technology to be eligible for add-on payments, Medicare law and regulations require that it meet three criteria: it must be new, have significant additional cost as evidenced by exceeding a cost threshold, and represent a significant clinical improvement.

Section 503 of the MMA provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. However, CMS continues to resist approval of new technologies and considers only a few technologies a year for add-on payments.

For several years there have been ongoing discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to as ICD-10) were developed as replacement classification systems. Despite recommendations that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS HHS has not yet moved forward to adopt the ICD-10 classification upgrades. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading. In light of this inaction, CHA is concerned about CMS' ability to implement add-on payments for new services and technologies in the near future. HHS should take the necessary steps to

avert the impending coding crisis and avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. CHA strongly recommends that the Secretary undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS expeditiously

Direct Graduate Medical Education

Exclusion of Didactic Training
For hospital mergers involving direct graduate medical education (DGME) costs, CMS proposes effective for cost-reporting periods beginning on or after October 1, 2006, using full-time equivalent (FTE) resident data and per resident amount (PRA) data from the most recently settled cost reports of the merging hospitals. CMS stated that it would be less administratively burdensome to use these data, instead of using the DGME count or residents and PRA from each merged hospital's base-year cost report, since these data are more recent and, therefore, more accessible.

CMS also stated that resident training that occurs at non-hospital sites must be related to patient care if a hospital wishes to count that time for DGME and IME payment purposes. Resident time spent in didactic activities that often occur in associated medical schools such as educational conferences, journal clubs and seminars would be specifically excluded. CMS notes that its statement in a previous letter on this topic "implying that didactic time spent in non-hospital settings could be counted for direct GME and IME ... was inaccurate." CMS further notes that time spent in these activities could be counted for DGME purposes if they occur in a hospital; however, the counting prohibition applies for IME payments regardless of where the educational activity occurs.

In stark contrast to the broad interpretation included in 1999 guidance from the Director for the Division of Acute Care, CMS is now declaring that this time is "not related to patient care." It seems that CMS is looking for a way to reimburse programs less, and has combined this statement with the requirements of an memorandum of understanding (with faculty mentoring non-hospital rotations) to bend the definition of didactic time in order to do so. The costs to the program of the resident's salary and benefits, plus teaching costs, do not change if the resident spends lunch hour at a conference or sits with an attending to discuss a topic from 5-6 pm. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs.

CHA strongly urges CMS to withdraw this change and in doing so to recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

OTHER CONCEPTS

Health Care Information Transparency Initiative
In 2006, the Department of Health and Human Services (HHS) proposes to launch a major health care information transparency initiative. HHS intends to identify several regions in the United

States where health care costs are high and where there is significant interest in reducing those costs and improving health care quality. HHS plans to use its leadership role in health care policy to help lead change in those areas.

While progress has been made in quality transparency, similar information on hospital pricing is less accessible. CMS discusses the difficulties in providing meaningful information for health care consumers and offers several options to consider. Proposals offered by CMS include:

- Publishing a list of hospital charges, either for every region of the country or for selected regions of the country.
- Publishing the rates that Medicare actually pays to a particular hospital for every DRG, or for selected DRGs, that could be adjusted to take into account the hospital's labor market area, teaching hospital status and DSH status.
- Establishing conditions of participation for hospitals that relate to posting of prices and/or the posting their policies regarding discounts or other assistance for uninsured patients.
- Posting total Medicare payments for an episode of care. Under this proposal, CMS could include the costs for an inpatient hospital stay, physician payments (including the surgeon and the anesthesiologist), and payments for post-acute care services such as those provided in an inpatient rehabilitation facility, SNF or LTCH for a certain service (such as hip replacement).

People deserve meaningful information about the price of their hospital care. Because we agree that more can, and should be done to share hospital pricing information with consumers, hospitals are committed to sharing information that will help people make important decisions about their health care. It is important to acknowledge that because hospital care is unique, sharing pricing information is more challenging.

Providing *meaningful* pricing information to consumers is the most significant challenge hospitals, and CMS, face in increasing transparency of hospital pricing information. CHA supports the AHA's stated objectives for improving pricing transparency. The objectives should include:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;
- Explaining to consumers how and why the price of their care can vary; and Encouraging consumers to include price information as just one of several considerations in making health care decisions.

AHA recently released a position statement on hospital pricing transparency outlining steps to be taken to improve the pricing information available to health care consumers. CHA supports AHA's four steps represent the AHA's roadmap for pricing transparency.

Hospital Value-based Purchasing

The DRA requires CMS to develop a plan to implement hospital value-based purchasing (pay-for-performance) beginning in FY 2009. The plan must consider the following issues:

- Measure development — the ongoing development, selection and modification process for measures of quality and efficiency in hospital inpatient settings;
- Data infrastructure and refinement — reporting, collecting and validating of quality data;
- Incentives — the structure of payment adjustments, including the determination of thresholds for improvements in quality that would substantiate a payment adjustment, the size of such payments and the sources of funding for the payments; and
- Public reporting — disclosure of information on hospital performance.

Because hospitals are committed to providing safe, effective, patient-centered, timely, efficient and equitable care to all patients, it is important that the development of a value-based purchasing system for Medicare be well thought out.

The HQA is not only accomplishing its goal of making standardized, easy-to-understand information available to the public, but also is reducing the measurement "babble" that had been generated by a large variety of separate organizations asking hospitals to produce quality information.

To be effective, incentive approaches must align hospital and physician incentives, encouraging all to work toward the same goal of improving quality and providing effective, appropriate care. This is imperative. Incentive approaches rewarding improvement can be successful only if physician and hospital performance can be successfully aligned, in terms of both performance and finances.

Incentive approaches to payment should use a system of rewards to increase payments or reduce regulatory burden for successful providers. Because the Medicare inpatient PPS already pays less than the cost of care for more than one-third of hospitals, incentives involving penalties should not be used. Additionally, rewards should be sizeable enough to cover the costs

Significant resources already have been invested in the HQA effort and the *Hospital Compare* Web site by all of the participants. The HQA effort must be viewed as the foundation on which we must continue to build, and it should be the foundation for any pay-for-performance program included in legislation. To base the pay-for-performance initiative on the work of a group other than the HQA would be duplicative, wasting significant knowledge and expertise.

Hospital-Acquired Infections

In the IPPS, complications, such as infections acquired in the hospital, can sometimes trigger higher payments — either as payment outliers or by assignment to a higher paying DRG. About 121 sets of DRGs split based on the presence or absence of a complication or comorbidity (CC), and DRGs with a complication or comorbidity generate higher Medicare payments. If an infection acquired during the beneficiary's hospital stay is one of the conditions on the CC list, the result may be a higher payment to the hospital under a CC DRG.

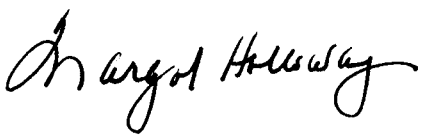
The DRA requires CMS to identify by October 1, 2007, at least two conditions that could lead to payment in a CC DRG. The conditions must be either high cost or high volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diag-

nosis, and reasonably preventable through the application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals would not receive additional payment for cases in which one of the selected conditions was not present on admission. That is, the case would be paid as though the secondary diagnosis was not present.

It is difficult to identify the confluence of known science and effective care processes to prevent infections. Until a broad array of expertise is brought together to consider what conditions, procedures and circumstances should be targeted for this change, it is impossible to know how to most effectively implement the provision. As the representative of America's hospitals and health systems, CHA would support any effort of this magnitude that includes the AHA as part of those discussions.

Thank you for the opportunity to provide comments on the proposed rule. If you have any questions, please contact me at (202) 488-4688 or mholloway@calhospital.org.

Sincerely,



Margot Holloway
Vice President, Federal Regulatory Affairs

Attachment 172

VAIDA HEALTH DATA CONSULTANTS

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May 10, 2006

MODELING FFY 2007 OUTLIER PAYMENTS

DATA SOURCES.

1. The MEDPAR 2005 computer file obtained from CMS. The file contains 13,715,186 records, each corresponding to a Medicare hospital discharge occurring in FFY 2005.

2. CMS FFY 2007 Impact File (Proposed Rule Version). This file produced by CMS shows the estimated level of FFY 2007 outlier payments by hospital (as percentages). It also shows the hospital-specific parameters used for calculating PPS payments, such as DSH and IME adjustment factors, cost to charge ratios (CCRs), wage indexes, etc.

3. The March 31, 2006 update of the HCRIS database. This database consists of Medicare cost reports beginning in Federal Fiscal Years (FFYs) 1996 through 2005.

REPLICATION OF THE CMS ESTIMATED 2007 OUTLIER PAYMENT LEVELS (IPPS 2007 PROPOSED RULE).

The regular and outlier FFY 2007 payments were estimated for 11,447,430 discharges in the MEDPAR database subject to IPPS. These are the same discharges used by CMS to generate the 2007 Proposed Rule Impact File[1]. Regular payments were calculated based on the proposed DRG weight, the patient discharge destination (for identifying transfers), the applicable proposed standardized amounts and the other hospital-specific parameters determining PPS payments. The latter are the wage index, the non-labor cost of living adjustment, and the DSH and IME adjustment factors. Each of these parameters has different values applicable to operating and capital payments. The parameters were obtained from the CMS Impact File.

Outlier payments were calculated inflating 2005 charges by 15.71 percent (the inflation factor used by CMS[2]), reducing charges to costs using the cost to charge ratios from the CMS Impact File and comparing costs to the proposed FFY 2007 fixed loss amount of $25,530. The latter was adjusted as appropriate on a hospital-specific basis. It should be noted that the Impact File cost to charge ratios are mostly from fiscal periods beginning in FFY 2004. Also, no allowance was made for the anticipated continued decrease in the CCRs.

With these assumptions, the FFY 2007 operating and capital outlier payments were estimated at 5.1 and 4.81 percent of the respective total payments, net of DSH and IME amounts. These estimates are in good agreement with the CMS figures of 5.1 and 4.87 percent, respectively. The dollar amount of FFY 2007 outlier payments was estimated at $4,774B.

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1 These are discharges subject to IPPS and with non-zero covered days and charges. The number of these discharges is the same as the number of "Bills" for all the hospitals in the Impact File.

2 The two-year inflation factor in the Proposed Rule is stated to be 15.15 percent. This is not consistent with the annual inflation ratio of 7.57 percent stated in the same Proposed Rule. The annual inflation rate of 7.57 percent translates into a 15.71 percent two-year rate.

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT USING THE MOST RECENT COST TO CHARGE RATIOS.

More recent cost to charge ratios were calculated from the latest cost reports available in the HCRIS database. Medicare inpatient operating costs were obtained from Worksheet D-1, Part II, Medicare inpatient capital costs from Worksheet D, Parts I and II and Medicare inpatient charges from Worksheet D-4. A comparison with the dates of the CCRs in the Impact File, presumably used to establish the proposed FFY 2007 fixed loss threshold, is shown in the table below.

Beginning in FFY	Number of Cost Reports Used for the Impact File CCRs	Percent of Cost Reports Used for the Impact File CCRs	Number of HCRIS Most Recent Cost Reports for Impact File Hospitals	Percent of HCRIS Most Recent Cost Reports for Impact File Hospitals
	(a)	(b)	(c)	(d)
2001	5	0.2%	3	0.1%
2002	39	1.4%	13	0.4%
2003	739	27.0%	92	2.6%
2004	1,949	71.1%	2,948	84.0%
2005	10	0.4%	453	12.9%
Unknown/Not Matching	780		13	
Total	3,522		3,522	

Table Notes: Column (a) numbers are based on matching Impact File CCRs with HCRIS CCRs for fiscal periods beginning between 2001 and 2005. If both operating and capital HCRIS CCRs were within 0.001 of their respective Impact File counterparts, the HCRIS cost report was considered to be the source for the Impact File CCRs. Percentages in columns (b) and (d) are based on the total of FFYs 2001-2005, i.e., unkown/not matching hospitals were not included.

Using the more recent HCRIS CCRs and the CMS assumptions listed above, the estimate of the fixed loss threshold is **$24,990**.

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT PROJECTING BOTH CHARGE AND COST INFLATION.

Outlier payments are calculated from costs. Costs are determined by applying a cost to charge ratio to actual charges. It follows that accurate outlier estimates require projecting **both** costs and charges.

An additional complication is the inevitable lag between CCRs that can only be determined retrospectively at the end of an elapsed cost reporting period and the current charges to which they are applied. Historically, CMS has projected outlier payments by projecting only costs or only charges and ignored the time lag problem. This approach works well in periods when cost and charges move more or less in tandem. When costs and charges change at significantly different rates, relying on only one measure of inflation can result in either outlier over- or underpayments[3]. An alternative methodology that overcomes these shortcomings is described below.

In order to account for the time lag problem, cost to charge ratios were projected from the most recent fiscal period in the March 31, 2006 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining FFY 2007 outlier payments. The CMS Program Memorandum A-03-058 dated July 3, 2003 instructs Fiscal Intermediaries to update the CCRs "not later than 45 days after the date of the tentative settlement or final settlement used in calculating the CCRs". Combining this deadline with the maximum of eight months between the end of the cost reporting period and tentative settlement, it is reasonable to expect CCRs to be updated no later than nine months after the end of the cost reporting periods. Assuming a nine-month lag in updating CCRs, FFY 2007 outlier payments will be based partly on 2005 and partly on 2006 ratios, depending on the fiscal period ending date (FPE). Hospitals with a January FPE will have their CCR updated to the FPE January 2006 value by October 31, 2006. Their FFY 2007 outlier payments will be based on the FPE January 2005 CCR for one month (October 2006) and on the FPE January 2006 CCR for the remaining eleven months. Similarly, FFY 2007 outlier payments for hospitals with a February FPE will be based on the 2005 CCR for two months and the 2006 CCR for ten months, and so on. Hospitals with a December FPE would have their FFY 2007 outlier payments based entirely on the FPE December 2005 CCR.

The cost inflation factor for projecting CCRs was determined from the costs reports of a cohort of 3,253 matched hospitals for periods beginning in FFYs 2002, 2003 and 2004. All three costs reports were available for each hospital from the recent update of HCRIS and covered a full twelve months. The 2002-2004 aggregate annual rate of increase in the cost per discharge for these hospitals was 5.69 percent[4]. This cost inflation factor and the CMS charge inflation factor of 7.57 percent were used to project cost to charge ratios over the time periods described above. The projected CCRs were applied to projected FFY 2007 charges to simulate the determination of costs for FFY 2007 outlier payments. The estimated fixed loss amount that would result in 5.1 percent outlier payments in this scenario is **$24,000**. It should be noted that this model (as well as all the ones discussed here) does not take into account the potential impact of outlier reconciliation. The model assumes FFY 2007 outlier payments based on costs determined using pre-2007 CCRs. If outlier payments were adjusted retrospectively based on FFY 2007 "true" costs determined using 2007 CCRs, final outlier payments would be lower (assuming a continuing trend of decreasing cost to charge ratios).

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3 Of course, regardless of methodology, over- or under estimates of outlier payments may result from cost and/or charge inflation projections -usually based on the assumption that historical values are a reasonable indicator of future trends- that turn out to be inaccurate.

4 An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 2,791 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2006 HCRIS update.

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT PROJECTING ONLY COST INFLATION.

This is the methodology CMS used for the FFYs 1994-2002. For projecting FFY 2007 outlier payments it consists of applying historical CCRs to FFY 2005 charges to determine FFY 2005 costs. These costs are projected forward to FFY 2007 using a cost inflation factor. However, the "cost inflation only" approach ignores the time lag problem. This may result in underestimating FFY 2007 costs for outlier payment determination and, therefore, underestimating the FFY 2007 fixed loss threshold. The underestimate results from using historical CCRs generally more recent than the CCRs actually available in 2004[5].

The cost inflation approach using an annual cost inflation factor of 5.69 percent and the Impact File CCRs resulted in a FFY 2007 estimated fixed loss amount of **$23,055**. If the most recent CCRs from the HCRIS database were used instead, the estimated FFY 2007 fixed loss amount was **$22,645**.

ESTIMATE OF THE FFY 2006 OUTLIER PAYMENTS

The 2007 IPPS Proposed Rule states that FFY 2006 outlier payments are now estimated at 4.71 percent of total DRG payments. Using the "charge inflation only" model and the Impact File cost to charge ratios, the outlier payment level was estimated at 4.64 percent, essentially replicating the CMS finding. Using the same model, the 2006 fixed loss amount that would result in a payment level of 5.1 percent was estimated at **$21,530**.

The FFY 2006 fixed loss amount was estimated using all the other models described above. Still using the "charge inflation only" but substituting the most recent HCRIS CCRs for the Impact File ratios, the fixed loss threshold was estimated at **$21,160**. It should be noted that the most recent CCRs used in these model were selected by taking into account their applicability to FFY 2006. For example, assuming a nine-month lag in updating CCRs, hospitals with fiscal periods ending in June 2006 had their first six months of FFY 2006 outlier payments based on the June 2004 FPE cost to charge ratio, and the last six months based on the June 2005 FPE ratio. Even if the June 2005 FPE ratio was available from the HCRIS database, the CCR used in this model was an average of the 2004 and 2005 ratios weighted by the number of months of usage in FFY 2006.

If both cost and charge inflation are taken into account, and assuming a nine-month lag in updating CCRs, the FFY 2005 fixed loss threshold amount was estimated at **$21,275**.

Using the "cost inflation only" models the fixed loss amounts were estimated at **$20,460** and **$20,095**, based on Impact File and most recent HCRIS cost to charge ratios, respectively. Because of

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5 This discussion assumes charges increasing at a faster pace than costs. In that case, because FFY 2007 "costs for outlier payment determination" are obtained by applying CCRs from earlier periods to FFY 2007 charges, 2005 "costs" should be determined with similarly lagged CCRs.

The next to last paragraph on page 4 of the outlier report should read:

"If both cost and charge inflation are taken into account, and assuming a nine-month lag in updating CCRs, the FFY 2006 fixed loss threshold amount was estimated at **$21,275"**

instead of

"If both cost and charge inflation are taken into account, and assuming a nine-month lag in updating CCRs, the FFY 2005 fixed loss threshold amount was estimated at **$21,275"**

the problems with the "cost inflation only" model noted for the FFY 2007 estimates, i.e. not taking into account the lag in updating CCRs, it is quite likely these amounts are underestimated.

Both FFY 2006 and 2007 results and underlying assumptions are summarized in the tables on the following pages.

CALCULATION OF THE FFY 2005 FIXED LOSS AMOUNT THAT WOULD HAVE RESULTED IN OUTLIER PAYMENTS OF 5.1 PERCENT

The level of outlier payments actually made in 2005 can be determined from the 2005 MEDPAR data. The operating outlier payment, if any, is explicitly shown for each Medicare discharge. The regular DRG operating payment can be easily determined from data in the file. Specifically, the operating payment net of indirect medical and disproportionate share adjustments is the DRG PRICE less CAPITAL, DSH and IME payments. The amounts shown in capitals are all fields in the MEDPAR records. The total outlier payments made in 2005 amounted to 3.051B[6]. This represents 3.8 percent of total Medicare IPPS payments net of indirect medical and disproportionate share adjustments. The result is significantly different from the CMS estimate of 4.1 percent. The 3.8 percent level of outlier payment translates into a shortfall of $1.1B.

The outlier amounts that should have been paid could be calculated from the MEDPAR data if the cost to charge ratios actually used were available. To my knowledge there is no public data source for them. An alternative would be to estimate the CCRs from other data sources, e.g., HCRIS. However, this would involve assumptions about the rates of cost and charge inflation. In order to avoid dependence on such assumptions the CCRs were estimated from the MEDPAR file itself. The comparison of any two outlier payments *calculated using the same CCRs* allows the determination of the CCR:

$O_1 = 0.8 \times (OPCCR \times C_1 - D_1 - AFL)$

$O_2 = 0.8 \times (OPCCR \times C_2 - D_2 - AFL)$

where O = outlier payment, C = charges, D = DRG payment, AFL = adjusted fixed loss amount and OPCCR = operating cost to charge ratio.

Note that AFL is actually dependent of the cost to charge ratios, but since it cancels out of the final equation, this fact can be ignored

Subtracting the second equation from the first and solving for OPCCR:

$$OPCCR = [(O_2 - O_1) / 0.8 + (D_2 - D_1)] / (C_2 - C_1)$$

A similar calculation can be carried out for the capital cost to charge ratio. This method was used to determine the CCRs by arraying all outlier payments made to a hospital during a given quarter in

6 The aggregated amount of outlier payments for the 11,447,430 discharges in the 2005 MEDPAR selected as described on Page 1.

increasing order of the covered charges. The calculation shown above was performed by comparing each outlier payment in the array to the outlier payment with the highest covered charges and, again, to the outlier payment with the lowest charges. The median of the CCRs thus obtained was considered to have been the CCR used to determine outlier payments for the quarter and hospital under consideration. If the actual CCR remained the same during the entire quarter, the method above should in principle determine it exactly. If the CCR did change during the quarter, the calculation yields an approximate "effective" CCR. (The date of discharge shown in the public version of MEDPAR is limited to the quarter of discharge). The approach outlined above can be applied only when a hospital had at least two outliers in a given quarter. For hospitals with less than two outliers in a quarter, the CCR ratios were taken from the CMS Impact File for FFY 2005 (the Final Rule version).

In order to validate the CCRs obtained as described above, they were used to calculate "simulated" 2005 outlier payments based on the fixed loss amount of $25,800 effective in FFY 2005. The total amount of "simulated" payments was $3,036B compared with the actual amount of $3,051B[7]. The CCRs were then used to calculate the 2005 fixed loss amount that would have resulted in a 5.1 percent outlier payment level. The result was **$19,790**.

7 The comparison was limited to cases when outlier payments were actually made. Simulated payments for all cases are slightly higher ($3,132B). This may reflect situations when outlier payments were denied for not being submitted in accordance with Medicare laws and regulations.

FFY 2007 ESTIMATED FIXED LOSS AMOUNTS AND UNDERLYING ASSUMPTIONS

METHODOLOGY	Data Source for Cost to Charge Ratios	Charge Inflation (Proposed Rule, Rate of Change from Jul-Dec 2004 to Jul-Dec 2005)	Cost Inflation	Change in Cost to Charge Ratios	Assumed Lag Between the Fiscal Period End and Effective Date of the CCRs	ESTIMATED FFY 2007 FIXED LOSS AMOUNT ($)
		(Per Year)	(Per Year)	(Per Year)		
Charges Projected From FFY 2005 to FFY 2007	CMS Impact File-Proposed FY 2007	7.57%	None	None	None	25,530
Charges Projected From FFY 2005 to FFY 2007	HCRIS 03/31/2006 Update	7.57%	None	None	None	24,990
Charges Projected From FFY 2005 to FFY 2007; Cost to Charge Ratios Projected to Simulate Effective CCRs for FFY 2007 Outlier Payments	HCRIS 03/31/2006 Update	7.57%	5.69% (From HCRIS Cost Reports 2002-2004)	-1.75%	Nine Months	24,000
Costs Projected From FFY 2005 to FFY 2007	CMS Impact File-Proposed FY 2007	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	23,055
Costs Projected From FFY 2005 to FFY 2007	HCRIS 03/31/2006 Update	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	22,645

FFY 2006 ESTIMATED FIXED LOSS AMOUNTS AND UNDERLYING ASSUMPTIONS

METHODOLOGY	Data Source for Cost to Charge Ratios	Charge Inflation (Proposed Rule, Rate of Change from Jul-Dec 2004 to Jul-Dec 2005)	Cost Inflation	Change in Cost to Charge Ratios	Assumed Lag Between the Fiscal Period End and Effective Date of the CCRs	ESTIMATED FFY 2006 FIXED LOSS AMOUNT ($)
		(Per Year)	(Per Year)	(Per Year)		
Charges Projected From FFY 2005 to FFY 2006	CMS Impact File-Proposed FY 2007	7.57%	None	None	None	21,530
Charges Projected From FFY 2005 to FFY 2006	HCRIS 03/31/2006 Update	7.57%	None	None	None	21,160
Charges Projected From FFY 2005 to FFY 2006; Cost to Charge Ratios Projected to Simulate Effective CCRs for FFY 2006 Outlier Payments	HCRIS 03/31/2006 Update	7.57%	5.69% (From HCRIS Cost Reports 2002-2004)	-1.91%	Nine Months	21,275
Costs Projected From FFY 2005 to FFY 2006	CMS Impact File-Proposed FY 2007	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	20,460
Costs Projected From FFY 2005 to FFY 2006	HCRIS 03/31/2006 Update	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	20,095

HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

173

Carolyn F. Scanlan
President and Chief Executive Officer

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of Pennsylvania's 225 hospitals and health care systems, The Hospital & Healthsystem Association of Pennsylvania (HAP) welcomes this opportunity to comment on the proposed rule **"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates,"** as published in the April 25, 2006, *Federal Register.*

The Centers for Medicare & Medicaid Services (CMS) has proposed the most significant changes to the Medicare inpatient prospective payment system since its inception in 1983. The proposed changes redistribute approximately $1.4 billion within the inpatient payment system.

While the proposed rule has many components, there are four key areas within the rule that will significantly impact Pennsylvania hospitals and health systems:

- ✔ Recalibration of Diagnosis Related Group (DRG) Weights
- ✔ Refinement of DRGs Based on Severity of Illness
- ✔ Wage Index and Occupation Mix Adjustment
- ✔ Hospital Quality of Care

HAP commends the Centers for Medicare & Medicaid Services for working toward the refinement of the inpatient prospective payment system to ensure equal opportunity for return across the DRGs, as well as to afford equal incentive to treat all types of patients and conditions. However, HAP strongly urges CMS to consider a one-year delay in implementing refinements to the Medicare inpatient prospective system. **HAP is specifically recommending a one-year delay in implementing proposed changes to the DRG weights.** While HAP supports a move to cost-based weights, we believe there are flaws in the proposed methodology, modeling, and technical data used for refining the

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DRG payment system. A one-year delay would allow time to enable a more thorough analysis and to address flaws before implementation.

HAP also believes that more work must be done to assess the need and most appropriate approach for changing the patient classification system.

In addition to a one-year delay, HAP would encourage CMS to consider a simultaneous implementation of the DRG weight changes and new classification system (after thoughtful consideration and determination that a new classification system is necessary) over a three-year transition period.

Given the regulatory process, HAP does not believe that there has been adequate time for Pennsylvania hospitals to thoroughly analyze the proposed changes and assess impact to their individual facilities. Analysis that has been done has shown that even the slightest of changes in the proposed method results in potentially large changes to a hospital payment.

In essence—there is too much change, being proposed too fast. Such changes in the payment system deserve more thoughtful consideration and due diligence to ensure the end result will be the adoption of meaningful improvements to Medicare's inpatient prospective payment system. Our hope is that given the significant impact these proposed changes will have on the hospital field as a whole, that CMS will impose a one-year delay to afford CMS and the hospital field time to work collaboratively to address concerns.

With regards to the quality provisions in the proposed rule, while HAP supports the expansion of reporting of quality data, **HAP recommends that CMS begin with third quarter 2006 discharges. HAP also suggests that CMS not include measures in the validation mix for annual payment until after one full year of reporting.** This delay will allow hospitals to learn from the review of records and feedback about data abstraction during the first year.

HAP has enclosed more detailed comments on all sections of the proposed rule, which further delineate our concerns and recommendations.

HAP appreciates the opportunity to submit these comments and recommendations. If you have any questions regarding our comments, please feel free to contact me or Melissa Speck, director, policy development, at (717) 561-5356 or mspeck@haponline.org.

Sincerely,

Carolyn F. Scanlan

CAROLYN F. SCANLAN
President and Chief Executive Officer

CFS/dd

Attachment

The Hospital & Healthsystem Association of Pennsylvania
Detailed Comments on the
FY 2007 Inpatient Prospective Payment System Proposed Rule

PROPOSED CHANGES

DRG CHANGES

In response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC) to address the proliferation of physician-owned, limited-service hospitals, the Centers for Medicare & Medicaid Services (CMS) proposed the biggest changes to the calculation of diagnosis-related group (DRG) relative weights since the creation of the prospective payment system (PPS). These changes would significantly redistribute payments among the DRGs and among hospitals. Specifically, CMS proposes the use of hospital-specific relative values (HSRVs) and a modified version of cost-based weights rather than charge-based weights in fiscal year (FY) 2007. CMS also proposes an alternative patient classification system called consolidated severity adjusted DRGs (CS-DRGs), with implementation likely in FY 2008.

The hospital field supports meaningful improvements to Medicare's inpatient PPS. We believe that the hospital field and CMS share a common goal in refining the system to create an equal opportunity for return across DRGs which will provide an equal incentive to treat all types of patients and conditions. We also believe the system should be simple, predictable, and stable over time. One of the fundamental values of a *prospective* payment system is the ability of providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions. Another core feature of the PPS is clinically cohesive and meaningful DRGs that are somewhat intuitive for providers and coders to follow, and that reflect similar resource use within DRGs. And, ultimately, the inpatient PPS should foster innovation and best practice in care delivery. HAP believes that these are essential characteristics of a well-functioning PPS and it is within these policy goals that we evaluate CMS' proposal.

HAP would also like to emphasize that payment changes alone not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving low-income patients, practice similar forms of selection for outpatient services and drive up utilization for services. We strongly urge CMS to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider our comments on the interim report on the strategic plan. It is imperative that CMS continue the suspension of issuing new provider numbers to physician-owned, limited-service hospitals until the strategic plan developed has been fully implemented and Congress has had an opportunity to consider CMS' final report.

NEW DRG WEIGHTS: HSRVCC

CMS proposes an alternative to MedPAC's approach to HSRVs and cost-based weights that could be characterized as a short cut. CMS asserts that this combined methodology, known as the HSRV cost center methodology (HSRVcc), achieves similar results in a more

administratively feasible manner. But that is not the case. Specifically, the CMS proposal involves two major steps.

1. Develop, on a charge-basis, hospital-specific relative weights for each DRG. CMS established 10 cost center categories based on broad hospital accounting definitions: routine day costs; intensive care day costs; and eight ancillary cost centers. CMS calculated DRG relative weights for each of the 10 cost centers by DRG for each hospital and then used those hospital-specific weights for calculating national DRG weights. CMS' current process aggregates charges for all hospitals at the DRG level to calculate weights. CMS believes the new approach removes the variation introduced by hospital characteristics such as teaching, disproportionate share, location and size, among others.

2. "Scale" the charge-based DRG weights to "costs" using the national cost center cost-to-charge ratios (CCRs) developed from the cost report data (as opposed to using hospital-specific CCRs at the claim level). CMS believes this approach will remove the effect of different CCRs across departments within hospitals. CMS chose this methodology because the use of national average rather than hospital-specific departmental CCRs is administratively easier.

HAP supports the move to cost-based weights but believes CMS' proposed method is flawed. More work is needed to determine the best way to create cost-based weights. Hospitals are willing to work with CMS in a process to develop consensus around the right way to make this change. Below we discuss our detailed concerns and questions regarding the proposed HSRVcc methodology.

HSRVcc METHOD CONCERNS

HAP believes that more time is needed to develop a sound methodological approach to create cost-based weights and to understand their potential impact.

1. **Errors:** While analyzing CMS' proposed rule, HAP uncovered a series of data errors, inconsistencies across databases and questionable methodological choices. Further analyses commissioned by the American Hospital Association (AHA), the Association of American Medical Colleges and the Federation of American Hospitals and conducted by The Moran Company, Inc. to investigate these questions showed that small changes in method lead to large changes in DRG weights, signaling that the proposed changes are highly unstable.

   For instance, the following, more minor, inconsistencies were identified:

   - CMS inadvertently included organ acquisition costs in the data used to set weights for DRGs. These costs should be excluded. This error has a material effect on the resulting weight calculation for transplants. For example, CMS publishes a weight of 5.5466 for DRG 302 (Kidney Transplant), but with this correction The Moran Company calculates a weight of 3.0102.

   - CMS was inconsistent in its treatment of certain categories of hospitals between their calculation of the FY 2007 HSRVcc weights and the proposed CS-DRG weights, making it hard to directly compare the results. For example, hospitals in Maryland

were included in the FY 2007 MedPAR data used for the HSRVcc weight calculation and excluded from the CS-DRG calculation.

- The Moran Company used transfer-adjusted charges prior to calculating weights. It was CMS' policy to do this. However, it is unclear whether the weights published for CS-DRGs included this step.

- Data cleaning steps used were not always consistent with standard CMS practices (e.g., removal of cases with 0 charges, low volume DRGs, etc.).

- The cleaning steps applied to the cost report data were not consistent with the cleaning steps applied to the MedPAR claims data, which resulted in different hospitals being included in data sets used for the calculation of the weights and the calculation of the scalers to the weights. For example, hospitals in Maryland and hospitals without cost reports for FY 2003 were excluded from the cost report data used to calculate the scalers and included in the MedPAR file used to calculate the weights.

2. **Trimming:** CMS trimmed the cost center CCRs at 1.96 standard deviations from the geometric mean. We believe that this skews the CCRs, as the hospitals with high routine charge mark-ups are systematically removed from the calculation. This results in the exclusion of 198 hospitals' routine CCRs, accounting for over 26 percent of total routine charges. It also creates a mismatch between the CCRs used and the charges they are applied to, as the hospitals that are trimmed out of the CCRs are still included in the charges that are then reduced to costs and determine the cost shares.

3. **Weighting:** CMS also hospital-weighted rather than charge-weighted the calculation of the CCRs which in turn are used to calculate the scaling factors used to convert the charge-based relative weights to "cost." There are several issues with this approach:

    - This approach gives an equal weight to each hospital in the national cost-to-charge ratio calculation even though hospitals can range in size from fewer than 25 to more than 1,000 beds.

    - This method is inconsistent with the method of averaging used to develop the cost center-specific DRG weights to which the scaling factors are applied. For this part of the analysis, CMS calculated hospital-specific DRG relative weights, but then used a case-weighted average to develop the national value.

    - The hospital-weighted approach results in a 1 percent to 54 percent difference versus a charge-weighted approach in the resulting scaling factors used for the conversion to cost.

The above errors in the calculations over-weight CMS' routine cost shares and under-weight the ancillary cost shares, creating erroneously large swings in DRG weights. Table 1 illustrates how these methodological problems affect the factors used to scale the cost center-specific relative weights. This table shows the impact of trimming the cost center CCRs at 3.0 rather than 1.96 standard deviations from the geometric mean and charge-weighting

rather than hospital-weighting the calculation of the national average CCRs that are used in developing the scalers.

Table 1
Impact of Methodological Changes on "Scalers"
Published versus Revised with Methodological Changes

Scaler	CMS Published	Methodological Changes			Percent Change vs. Published
		Trimming Only	Weighting Only	Weighting/ Trimming	
Routine days	0.2881	0.2882	0.2646	0.2490	-14%
Intensive days	0.1919	0.1933	0.1668	0.1636	-15%
Drugs	0.0877	0.0884	0.0939	0.0970	11%
Supplies	0.1150	0.1142	0.1325	0.1383	20%
Therapeutic	0.0384	0.0381	0.0390	0.0388	1%
Operating room	0.0812	0.0838	0.0861	0.0888	9%
Cardiology	0.0241	0.0246	0.0351	0.0371	54%
Laboratory	0.0670	0.0659	0.0681	0.0687	3%
Radiology	0.0427	0.0437	0.0460	0.0474	11%
Other services	0.0639	0.0600	0.0677	0.0712	12%

Source: Moran Company analysis.

These methodological problems have a large impact on the relative weight calculations at the DRG level. Table 2 shows, for key DRGs, how these methodological problems affect the DRG weights and, therefore, hospital payments.

Table 2
DRG Weights with Current Methodology vs. HSRVcc with Various Corrections
High Volume DRGs with Largest Changes in Weights Due to Corrections

				New DRG Weights: Published vs. Corrected			Change vs. Old Weights		
DRG (v24)	DRG Title	Number of discharges	Current Charged-based Weights w/v24 Grouper	CMS Published HSRVcc Weight	HSRVcc w/ Technical Corrections Only	Corrected, Weighted and Trimmed CCRs	DRG Weight Change Current Method vs. Published	DRG Weight Change Current vs. Corrected, Weighted, and Trimmed	Published vs. Corrected, Weighted, and Trimmed
430	PSYCHOSES	74,871	0.6561	1.2316	1.2416	1.1110	[illegible]	[illegible]	[illegible]
12	DEGENERATIVE NERVOUS SYSTEM DISORDERS	56,042	0.8983	1.0105	1.0099	0.9635	12.5%	7.3%	-4.7%
475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	119,513	3.4630	3.8279	[illegible]	3.8573	[illegible]	[illegible]	[illegible]
277	CELLULITIS AGE >17 W CC	118,691	0.8676	1.0015	1.0026	0.9578	15.4%	10.4%	-4.4%
87	PULMONARY EDEMA & RESPIRATORY FAILURE	86,508	1.3854	1.6310	1.5324	1.4899	[illegible]	[illegible]	[illegible]
320	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W CC	224,491	0.8611	0.9538	0.9544	0.9162	10.8%	6.4%	-3.9%
294	DIABETES AGE >35	97,122	0.7750	0.8642	0.8636	0.8307	11.5%	[illegible]	[illegible]
296	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W CC	246,948	0.8213	0.9041	0.9042	0.8701	10.1%	5.9%	-3.8%
79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	159,894	1.5939	1.7331	1.7359	1.6680	[illegible]	[illegible]	[illegible]
243	MEDICAL BACK PROBLEMS	100,498	0.7888	0.8680	0.8693	0.8363	10.0%	6.0%	-3.7%
554	OTHER VASCULAR PROCEDURES W CC W/O MAJOR CV DX	77,003	2.0890	1.9483	1.9560	2.0085	[illegible]	[illegible]	[illegible]
110	MAJOR CARDIOVASCULAR PROCEDURES W CC	57,436	3.8616	3.6419	3.6558	3.7563	-5.7%	-2.7%	3.1%
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG	119,991	1.4508	1.1670	1.1732	1.2380	[illegible]	[illegible]	[illegible]
544	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY	444,118	1.9514	1.8941	1.9047	2.0147	-2.9%	3.2%	6.4%
551	PERMANENT CARDIAC PACEMAKER IMPL W MAJ CV DX OR AICD LEAD OR GNRTR	53,717	3.0391	2.6339	2.6481	2.8453	[illegible]	[illegible]	[illegible]
552	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT W/O MAJOR CV DX	81,744	2.0837	1.7670	1.7771	1.9468	-15.2%	-6.6%	10.2%
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG	91,846	1.1117	0.7862	0.7918	0.8737	[illegible]	[illegible]	[illegible]
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX	123,550	2.8755	2.1323	2.1499	2.4236	-25.8%	-15.7%	13.7%
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	58,009	5.2591	4.1471	4.1795	4.7999	[illegible]	[illegible]	[illegible]
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	191,677	2.1920	1.4299	1.4456	1.7238	-34.8%	-21.4%	20.6%

Source: Moran Company analysis of FY 2007 proposed inpatient PPS rule. Uses FY 2005 MedPAR.
Notes: High volume DRGs defined as over 50,000 cases. Those included in the table were those with the greatest absolute change in weight moving from the CMS published DRG weight to the DRG weight calculated by trimming CCRs at 3.0 standard deviations, using weighted CCRs, and correcting for technical errors.

These changes have a material impact on hospital payment. CMS' method for weighting and trimming redistributes $1.4 billion dollars among hospitals. Charge-weighting the CCRs and trimming them at three standard deviations would reduce the shift in dollars to $900 million—a reduction of ***half a billion dollars***, or 33 percent. This highlights the need for more work to validate each methodological step to understand how it affects payment and ensure it adds to "accuracy."

4. **Failure to Calculate Costs at the Claim Level:** CMS chose to use *charges* to initially calculate the relative weights at the DRG level and then a national scaler to make the conversion to "cost-based" weights. The national scaler converts the 10 cost center charge-based weights to one national weight using the actual share of costs across departments. CMS maintains that this adjusts for differential mark-ups across hospital departments. In contrast, MedPAC estimated *costs* at the claim level to calculate relative weights. CMS provided no validation of the methodological shortcut they propose.

5. **Cost Centers:** CMS aggregates charges into 10 cost centers for each DRG, then applies a cost-center level CCR (derived from the cost reports) to charge figures (from claims data). But because hospitals often report charges on the cost reports differently than charges on the claims, the cost-center level CCRs are calculated based on a different set of charges than the charges to which the CCRs are later applied. We believe this may materially distort the DRG weights and needs to be thoughtfully considered and accounted for in any methodology. If CMS is going to move to cost-based weights, regardless of the methodology, hospitals will

need time to align their mapping of cost centers into departments or cost categories for purposes of cost reporting with that of claims reporting.

6. **Validation:** As mentioned above, CMS provided no analysis to validate that the proposed changes result in better payment policy. While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone indicates the need for further analysis and study. CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the result, including:

    - Compare CMS weights to MedPAC's HSRV-cost approach;
    - Compare CMS weights to an approach using standardized costs (as opposed to HSRV);
    - Compare CMS weights-to-weights calculated by estimating costs at the claims level using the 10 cost center approach;
    - Evaluate alternative methodologies for estimating costs (e.g., method used by New York state's Medicaid program);
    - Compare stability of weights over time; and
    - Determine whether payment policy is improved.

    Assessment of "payment accuracy" conducted by The Moran Company as well as The Health Economics and Outcomes Research Institute (THEORI), a division of the Greater New York Hospital Association, finds the CMS HSRVcc approach to be not at all to marginally better than the current system. Fixing the major methodological flaws yields minimal improvement, according to THEORI. CMS' HSRVcc approach actually creates new areas of care where systematic incentives for specialization could occur. This analysis raises significant questions about CMS' approach and further analysis should be conducted before any changes to the current charge-based methodology are made. These analyses will help determine the most effective and administratively feasible approach for a shift to cost-based weights in FY 2008.

NEW PATIENT CLASSIFICATION: SEVERITY OF ILLNESS

CMS also proposes moving to an entirely new patient classification system beginning in FY 2008 *or earlier*. Currently, Medicare uses 526 DRGs to classify all Medicare patients. CMS considered use of 3M's all-patient refined DRGs (APR-DRGs) as an alternative to its current DRGs, which would increase the number of categories to 1,258. However, CMS ultimately proposed refining the APR-DRG system by consolidating APR-DRGs into fewer categories. This would result in a new DRG system with 861 consolidated severity-adjusted DRGs, or CS-DRGs.

HAP believes that the need for and best approach to changing the patient classification system has not been concretely and objectively demonstrated. More careful analysis is needed, along with greater access to the specifics of CMS's methodology and the new GROUPER. Below we discuss our detailed concerns and questions about this proposal.

CS-DRG METHOD CONCERNS

1. **Validation:** It is unclear whether there is a need for a new patient classification system. More work is needed to assess the proposed system and others that might be considered. As

with the HSRVcc proposal, CMS provided no analysis that shows that the proposed changes result in an improved hospital payment system compared to the existing DRG system or APR-DRGs.

CMS must test the degree to which the variation in costs within cases at the DRG level is reduced under both CS-DRGs and APR-DRGs. Payment classifications that still exhibit a high degree of cost variation should be identified and potentially revised. We suggest comparing the distribution of the coefficient of variation at the DRG level for various grouping approaches.

For instance, CMS chooses to collapse the tier-four cases within major diagnostic categories (MDCs). It is unclear whether all of the tier-four cases are clinically cohesive enough to be combined and whether consolidation adequately considers variations in resource requirements. CMS also aggressively collapses the DRGs with low Medicare volume such as obstetrics, psychiatric and substance use services without any discussion of the potential ramifications for other payment systems, such as other Medicare PPSs, Medicaid and the private sector that often bases payment off the Medicare inpatient DRG system. CMS believes that a new patient classification system that distinguishes more-sick from less-sick patients will reduce the "cherry picking" of healthy patients, but there may be other, easier ways to accomplish this. For example, CMS embarked on a new way to differentiate patients last year based on the absence or existence of a major cardiovascular diagnosis, but did not discuss the possibility of other similar, less disruptive changes to the system as an option in this year's rule.

Even more fundamentally, today's DRG system was created to distinguish the resource use required among patients. It has been modified over time to reflect changes in clinical practice and technology. The APR-DRG system is based on severity of illness, not necessarily the resource use required. The implications of moving from a resource-based system to a severity-based payment system must be more fully explored and understood.

2. **Budget Neutrality Adjustment:** CMS suggests in the proposed rule that it would reduce payments to hospitals by instituting a budget neutrality adjustment to offset the fact that case mix may increase because of improved coding rather than actual changes in acuity. However, CMS did not propose an adjustment or even a methodology for determining an adjustment. CMS often institutes such adjustments that are based on assumptions but never checked or later corrected. We recommend that CMS hold off on such an adjustment until there is evidence that one is needed.

3. **Availability of the GROUPER:** The proprietary nature of the proposed CS-DRG GROUPER is of concern. The current DRG GROUPER logic has been in the public domain since the inception of the PPS. Without the new GROUPER logic, it is virtually impossible for the hospital field to thoroughly analyze the system and comment—without access to the new GROUPER, we have no understanding of how and why patients fall into certain CS-DRGs and cannot evaluate whether it represents policy improvement. If CS-DRGs are adopted and the GROUPER remains proprietary, HAP would be limited in our ability to educate and assist our member hospitals. Moreover, a single company's monopoly would be both more expensive and more difficult to integrate into our hospitals' existing systems. Maryland hospitals report a GROUPER price of $20,000 per hospital with the ultimate price varying based on criteria such as whether it is used on a mainframe or PC. As with all

previous and current DRG GROUPER logic, we urge CMS to place any new classification system in the public domain.

4. **Too Few Diagnoses and Procedures Considered:** We are concerned that CMS' GROUPER does not use all diagnoses and procedures that affect a patient's severity of illness and/or the resources utilized. The current DRG GROUPER only considers nine diagnoses and up to six procedures. Hospitals submit claims to CMS in an electronic format. The HIPAA compliant electronic transaction 837i standard allows up to 25 diagnoses and 25 procedures. Many fiscal intermediaries are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the GROUPER to assign a DRG.

   Capturing all diagnoses and procedures meeting the definitions of reportable secondary diagnoses and procedures will provide a more complete picture of patient complexity. As CMS considers methodologies for refining the patient classification system, the number of secondary diagnoses may be an important factor in determining differences in patient characteristics. This is particularly true of patients with many chronic illnesses that add to the complexity of treating them.

HAP supports meaningful improvements to Medicare's inpatient PPS. We believe the hospital field and CMS share a common goal in refining the system to create an equal opportunity for return across DRGs which will provide an equal incentive to treat all types of patients and conditions. However, more time is needed to understand the significant proposed policy changes, which redistribute from $1.4 to $1.7 billion within the inpatient system. Analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. Moving forward requires thoughtful change. Specifically, HAP supports the following:

- **One-year Delay:** HAP supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. HAP and Pennsylvania hospitals are committed to working with CMS over the next year to address these concerns.

- **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

- **A New Classification System Only if the Need Can Be Demonstrated:** HAP does not support a new classification system at this time, as the need for a new system is still unclear. More work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

- **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes. For example, of the 2,566 hospitals that would experience an increase in

payment using the HSRVcc[1] methodology alone, 48 percent would experience a net loss when CS-DRGs and HSRVcc are done together. Of the 859 hospitals that have a decrease in payment under the HSRVcc methodology alone, 33.9 percent would become overall winners when CS-DRGs and HSRVcc are done together.

- **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals. We recommend that CMS provide a three-year transition with a blend of the old DRG weights and the new DRG weights. In the first year, hospitals would be paid based on an average of DRG weights: 75 percent of the old weights; 25 percent of the new weights. The second year would be 50 percent of each, and the third year would be 25 percent of the old weights and 75 percent of the new weights. Another method of transition is dampening the reduction for DRGs with significant decrease in relative weights similar to the dampening of APC weights in the outpatient PPS. Dampening could be more feasible—especially if a significant change to the classification system is made—because it does not require CMS to calculate payments using two different systems.

  We further believe that a stop loss should be instituted as part of this transition. This would be similar to the approach currently used under the inpatient psychiatric PPS whereby no hospital can receive less than 70 percent of what they would otherwise have been paid under the old system. In combination with the DRG blend or dampening, this would result in less significant losses in the first year than in the last year of the transition. To avoid having to run all claims under both DRG weights, CMS could establish a payment-to-cost ratio for each hospital in FY 2006 and use that as a base against which to compare payments under the new system.

- **Collaborative Approach to Moving Forward**: HAP commits to working with the AHA, other hospital associations and CMS to develop and evaluate alternatives for new weights and classifications.

DRG RECLASSIFICATIONS

DRGs: Pancreas Transplant. We agree with the proposed coding changes for DRG 513 (Pancreas Transplant), which removes the requirement that pancreas transplant patients also have kidney disease. This change is consistent with the newly approved National Coverage Determination (NCD) to cover pancreas transplants alone as reasonable and necessary under limited circumstances for patients with Type I diabetes.

DRGs: Dual Array Implantable Neurostimulators for Deep Brain Stimulation. We oppose CMS' recommendation to keep the implantation of dual array implantable neurostimulators for deep brain stimulation in DRG 1 (Craniotomy Age >17 with CC) and DRG 2 (Craniotomy Age >17 without CC). CMS should recognize the higher resources associated with this technology.

DRGs: Carotid Artery Stents. We oppose the proposed delay in making any changes to carotid artery stent cases. The higher costs associated with carotid stents should be recognized within the existing DRG system.

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[1] Source: Moran Company analysis of 2004 MedPAR under FY 2007 payment policies using weighted CCRs and trimming CCRs at 3.0 standard deviations.

DRGs: Cardiac Resynchronization Therapy, Defibrillators (CRT-D). We agree with the proposal to add code 37.74 (Insertion or Replacement of Epicardial Lead [Electrode] into Atrium) to the DRG logic so that all types of defibrillator devices and lead combinations would be included in the following DRGs:

- DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheter);
- DRG 535 (Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock); and
- DRG 536 (Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock).

This change would bring the DRGs into alignment with the change in coding advice to assign code 37.74 in conjunction with implantation of CRT-D defibrillators.

Application of Major Cardiovascular Diagnoses (MCVs) List to Defibrillator DRGs. We oppose the proposal to delay refining defibrillator DRGs based on MCVs. We believe it is appropriate for CMS to apply a clinical severity concept similar to the approach used in FY 2006 to refine cardiac DRGs to an expanded set of DRGs (e.g., defibrillator DRGs) based on the presence or absence of an MCV.

DRGs: Hip and Knee Replacements. For FY 2006, new codes were created to differentiate between new and revised hip and knee replacements. In addition, more specific codes were created to identify the joint components replaced. After publication of the FY 2006 inpatient PPS final rule, a number of commenters advised CMS that the DRG logic for DRG 471 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) included knee and hip procedures that are not bilateral or do not involve multiple major joints. We agree with CMS' proposal to remove the codes from DRG 471 that do not capture bilateral and multiple joint revisions or replacements.

DRGs: Severe Sepsis. We agree that providers have found the coding of systemic inflammatory response syndrome (SIRS), sepsis and severe sepsis confusing in the last few years. The classification of these conditions has changed several times during this period. We concur that data have not been consistent and that a new DRG for severe sepsis would be inappropriate. However, we recommend that a change be made so patients with severe sepsis associated with respiratory failure requiring mechanical ventilation may be properly recognized. The ICD-9-CM classification instructions require that these patients be coded with the systemic infection as the principal diagnosis. The infection codes do not group to DRG 475 (Respiratory System Diagnosis with Ventilator Support) despite the use of resource-intensive mechanical ventilation (procedure code 96.7). This results in a significant loss of reimbursement for these patients.

Since the change in coding sequencing of these patients, the Coding Clinic Editorial Advisory Board has discussed this issue several times. In addition, several proposals have been submitted to the ICD-9-CM Coordination and Maintenance Committee to allow the sequencing of respiratory failure as the principal diagnosis. To date, no changes have been made. At this point, reverting the sequencing instructions would be confusing to coders and would once again disrupt trend data.

Instead, we recommend considering mechanical ventilation as a pre-MDC DRG on the basis of the procedure code. If this is not possible, we recommend that CMS add systemic infections (038.xx,) as acceptable principal diagnoses for DRG 475 when reported in conjunction with mechanical ventilation or tracheostomy.

DRGs: Complications/Comorbidities (CC) Categories 403-404. Effective October 1, changes have once again been made to the definition of the fifth-digits for categories 403 (Hypertensive Chronic Kidney Disease) and 404 (Hypertensive Heart and Chronic Kidney Disease). Prior to October 1, 2005, a fifth digit of "0" indicated "without chronic renal failure," while a fifth digit of "1" indicated "with chronic renal failure." While all patients in categories 403 and 404 had chronic kidney disease linked to hypertension, only those with a fifth digit of "1" had progressed to the point of kidney failure. Effective October 1, 2005, the definition of the fifth digits changed to "with or without chronic kidney disease." This was confusing since all patients in categories 403 and 404 by definition were supposed to have a chronic kidney condition. The change also blurred the distinction between the patients with more severe kidney failure and those with less kidney damage. The most recent change for this year once again changes the meaning of fifth digit "0" to identify patients "with chronic kidney disease stage I through stage IV or unspecified," while fifth digit "1" identifies patients "with chronic kidney disease stage V or end stage renal disease." As such, Table 6E of the proposed rule has identified codes 403.10, 403.90, 404.10 and 404.90 as non-CCs. The stages of chronic kidney disease are a fairly new concept introduced into the ICD-9-CM classification last year, which physicians do not routinely document in the medical record. Many physicians still document the older and more common term "chronic renal failure," which translates into "unspecified stage" in the ICD-9-CM. More importantly, physicians differ in their opinion of what constitutes renal failure—whether it starts in the middle of stage III, stage IV or stage V.

While we understand that CMS may not want to consider a code that would include patients in the early stages of hypertensive kidney disease as a CC, because of the potential inclusion of more serious chronic renal failure patients in codes 403.10, 403.90, 404.10 and 404.90, we recommend that CMS instead rely on the supplemental code from category 585 (Chronic Kidney Disease) to recognize the CC.

Implementing a Modern Clinical Classification System. We continue to agree with CMS' assessment in the May 9, 2002, hospital inpatient PPS notice of proposed rulemaking that ICD-10 is an improvement over ICD-9-CM and will provide greater specificity and detail. We believe that CMS should continue with plans to implement ICD-10. Implementing the significant DRG changes is a temporary fix, and a more refined DRG system can only be accomplished with more specific clinical classification systems, capable of painting a more complete picture of a patient's condition and the services provided to treat that condition—namely ICD-10-CM and ICD-10-PCS.

LONG-TERM CARE HOSPITAL (LTCH) DRGS

HAP is very concerned about the proposed reweighting of the long-term care hospital (LTCH) DRGs for FY 2007. The projected payment cut resulting from the reweighting—1.4 percent—in combination with the payment cut resulting from the recent LTCH PPS final rule for 2007—7.1 percent—will cause substantial volatility for LTCH providers, and ultimately restrict access for patients needing long-term acute care services. It would be extremely difficult for any provider group to withstand an 8.5 percent cut in one year. By pursuing these changes, CMS is

misinterpreting MedPAC's estimate of 2006 Medicare margins for LTCHs and creating an extremely unstable regulatory environment for LTCHs. MedPAC projected a 7.8 percent Medicare margin for LTCHs in 2006 and recommended no market basket update for FY 2007. However, this MedPAC projection does not include two major policy changes that also decrease Medicare margins for LTCHs: the projection excludes the impact of the "25% Rule" limiting payments to co-located LTCHs and the new reductions associated with the LTCH short-stay outlier policy. Therefore, CMS goes too far with this proposal to reduce Medicare payments even further.

Given these considerations, we urge the agency to forgo the proposed 1.4 percent cut and instead implement the reweighting in a budget-neutral manner.

This would appropriately redistribute allocated funds among the payment categories to reflect current costs and omit the inappropriate modification of total payments due to unrelated considerations. **It is irrational to treat the LTCH PPS differently than other Medicare payment systems by failing to reweight the LTCH PPS in a budget-neutral manner.**

At this time, CMS should focus on developing further patient and facility criteria for LTCHs to ensure that patients who are clinically suitable continue to have access to the LTCH setting. We strongly support CMS' pursuit of a scientific foundation for these expanded criteria and are eager to review the recommendations currently under development by CMS' contractor the Research Triangle Institute.

HOSPITAL QUALITY DATA

In accordance with the requirements in the Deficit Reduction Act of 2005 (DRA), the Centers for Medicare & Medicaid Services (CMS) has proposed expansion of the 10 quality measure starter set and linked the reporting of a total of 21 quality measures to the CMS data warehouse to the hospital annual payment update (APU) for FY 2007. The focus areas of the 11 additional measures are acute myocardial infarction, heart failure, pneumonia, and surgical infection prevention (SIP). The SIP measures include administration of an antibiotic within one hour of incision and the discontinuation of antibiotics within 24 hours after the surgery has been completed.

The rule also proposes that the data collection for the expanded set of quality measures begin with discharges occurring in the first calendar quarter of 2006—January 1, 2006, discharges. This data must be submitted to the CMS data warehouse by no later than August 15, 2006 for hospitals paid under the CMS prospective payment system to receive their full market basket update. Failure to submit the data on these additional measures in the time frame proposed will result in those hospitals receiving the full market basket update minus 2 percent.

Timeframe Concerns – In reviewing the proposed rule, HAP would like to submit the following comments for consideration.

- The rule was published in the *Federal Register* on April 25, 2006, well after hospitals had finished or were finishing most of the abstraction for 1st quarter 2006 discharges and had already or were nearly ready to transmit that data to their respective performance measurement vendors.
- Comments on the rule are not due to June 12, 2006, but hospitals have to comply with the rule at or about the time comments are due in order to meet the requirements in the rule to have the first quarter discharge information in the warehouse by mid-August in order to qualify for the update.
- In order to meet the deadlines proposed in this rule, hospitals have to enter into agreements with their performance measurement vendors in order institute a process that requires them to reabstract medical records for the additional measures. The SIP measures are particularly problematic given that only 25 percent of all Pennsylvania hospitals eligible for the annual payment update are presently collecting and reporting these measures to the data warehouse. HAP believes that approximately another 25 percent of hospitals have been collecting the data but have not authorized their performance measurement vendors to transmit that data to the warehouse. The remaining 50 percent of Pennsylvania hospitals have not been collecting the data. With the proposed rule, the majority of these hospitals have put processes in place to collect the required data beginning with 2nd quarter 2006 hospital discharges, but these hospitals will need to go back and retrieve the necessary data from medical records for 1st quarter 2006 discharges. Hospitals will incur additional expenses that include costs associated with the work required by their respective performance measurement vendors and overtime costs that are required for staff needed to perform this work under an expedited timeframe.
- Although data is not required to be in the data warehouse until August 15, 2006, hospitals must have their data submitted to their performance measurement vendors no later than sometime between June 15 and June 30 depending on the performance measurement vendor. Performance measurement vendors have had to move back their cutoff dates to allow hospitals sufficient time to abstract medical records. At least 80 of the 163 eligible PPS hospitals have only been given about six weeks to meet the timelines in this proposed rule.
- Pennsylvania hospitals that under these tight timeframes to collect and report additional measures, particularly the SIP measures, are concerned about the education and training of medical record abstractors. They do not believe that they have been given sufficient time to ensure appropriate training of their medical record staff to ensure a high degree of accuracy in the data abstraction.

RECOMMENDATIONS:

In light of these identified problems with the retroactive nature of the proposed rule, **HAP requests that CMS require the submission of the additional measures, specifically the SIP measures, begin with 3rd quarter 2006 discharges and that the annual payment update be tied to successful transmission of the additional measures beginning with 3rd quarter discharges. HAP also recommends that these measures not be included in the formal validation process for the annual payment update until after one full year of reporting of**

the additional measures. HAP does support a review of the records by the Clinical Data Abstraction Center for these additional measures, especially the SIP measures to permit hospitals to obtain feedback about the data abstraction for learning purposes during the course of the year.

Since the DRA calls for further expansion of the measures reported to the data warehouse, HAP recommends that CMS develop a process that affords organizations sufficient time prospectively to begin collection and reporting of any additional measures that will be considered in an annual payment update or part of a value-based purchasing program for hospitals.

Chart Validation – HAP recognizes the importance of ensuring that the data reported by hospitals to the data warehouse is accurate and appreciates the volume of charts that must be reviewed by the CDAC in order to ascertain whether the reported data is reliable and valid. In the proposed rule, CMS has indicated that hospitals must pass validation of a minimum of 80 percent reliability based on the CMS chart-audit validation process for the first three quarters of data from calendar year 2005. CMS has combined the chart samples for the first three quarters of 2005, or a total of 15 charts into a single stratified sample to determine whether the 80 percent reliability is met. CMS has requested comments on its passing threshold, confidence interval, and sampling approach. The following comments were provided by Pennsylvania hospitals in response to the request for comments.

- Pennsylvania hospitals indicated a comfort level with the present number of medical records selected each quarter for validation as well as the random selection of those charts, meaning that in the five charts selected there may be more requests for one disease/condition than another.
- Pennsylvania hospitals also agreed with the minimum threshold passing score established by CMS. However, given that CMS is proposing to combine the chart samples over several quarters in this rule and may propose the same in subsequent years, Pennsylvania hospitals strongly believe that they should have the opportunity to appeal all mismatches that they have with the CDAC and not just those situations where they have failed to meet the 80 percent threshold. Pennsylvania hospitals view this as vitally important to being able to ensure that they meet the 80 percent threshold in order to ensure a higher score in any one quarter than might compensate for lower score in another quarter.
- Pennsylvania hospitals also believe that the ability to challenge any mismatch between their organization and the CDAC represents an important learning opportunity for the organization. Specifically, Pennsylvania hospitals has indicated that having this ability to challenge mismatches may permit them to identify a problem, concern, issue, or pattern that could be rectified to prevent the same from occurring in subsequent quarters.
- CMS should consider a validation method that would exempt hospitals from having to undergo chart validation in some quarters if the hospital has consistently achieved very high validation scores in previous quarters. Potentially then, CMS could utilize some of its resources to request greater numbers of records for chart validation from those hospitals that are not consistently meeting the required 80 percent validation threshold.
- At a minimum, CMS should prospectively establish and communicate to the field which quarters will be used in the calculation of the validation threshold as this as critically important to receiving the APU as submission of the measures to the data warehouse in the required timeframes.

RECOMMENDATIONS

Pennsylvania hospitals strongly encourage CMS to allow hospitals to challenge any mismatches in the chart validation that they may have with CDAC in order to score as high as they possibly can in any quarter, learn from the process, and remedy any identified problems to prevent them from occurring in subsequent quarters. Additionally, Pennsylvania hospitals recommend that CMS consider a validation process that would focus more resources on those hospitals that are having difficulty in passing the validation thresholds on a consistent basis. Finally, going forward, CMS should prospectively establish and communicate to the field which quarters will be used in the calculation of the validation threshold.

Reconsideration Process

CMS has indicated that hospitals that do not meet the APU requirements for the applicable fiscal year may appeal this determination to the Provider Reimbursement Review Board and that any such requests for FY 2007 must be made by no later than November 1, 2006. CMS has also proposed that the November 1, 2006 deadline apply to FY 2005 and FY 2006 APU decisions and that a November 1 deadline would apply in all future fiscal years. Further, CMS is seeking public comment on the need for a more structured reconsideration process to precede any Provider Reimbursement Review Board appeal for FY 2008 and subsequent years.

RECOMMENDATIONS

Pennsylvania hospitals are supportive of a process that could potentially consider the reasons why a hospital was not able to meet the APU requirements for the applicable fiscal year and allow the hospital to meet the requirements to qualify for the APU. HAP believes that such a reconsideration process should be requested in writing by a senior level official of the organization, such as the chief executive, chief operating officer, and/or chief financial officer for the hospital. Specific reasons for these reconsiderations should include: the inability to timely submit data to the data warehouse as a result of CMS or vendor transmission failures; identification of information that may have been communicated inaccurately to CMS; and issues related to final chart validation scores as when the wrong chart was sent to the CDAC for validation and/or the charts sent to the CDAC were misplaced or lost which may have significantly adversely affected the validation scores for a particular quarter. HAP believes that Quality Improvement Organization staff could be extremely helpful to hospitals and to CMS in implementing any reconsideration process.

Future Measures

The DRA requires the expansion to other quality measures starting with FY 2008. The types of measures that may be added include: the HCAHPS® patient perception of care survey findings; structure measures as detailed in the recent Institute of Medicine report *Performance Measurement: Accelerating Improvement;* and outcome measures, specifically 30-day mortality for acute myocardial infarction and heart failure patients.

RECOMMENDATIONS

Hospital-specific patient outcomes reports have been publicly available in Pennsylvania for over 20 years. These hospital performance reports cover over 30-based code conditions and 19 DRGs. Outcomes included in these reports which are updated on a quarterly basis and available to the public include: risk-adjusted in-hospital mortality; risk-adjusted length of stay; risk-adjusted readmissions for any reason; risk-adjusted readmissions for complications, including infections; average hospital charge; and the percent of cases transferred to another acute care

facility. HAP does not believe that use of a 30-day risk-adjusted mortality for acute myocardial infarction and heart failure patients represents the best outcome measures that could be selected by Medicare to represent the quality of care delivered to patients in hospitals. HAP would strongly suggest that Medicare work with the Hospital Quality Alliance partners to identify outcome measures that better reflect the quality of hospital care. Additionally, use of the 30-day risk-adjusted mortality for acute myocardial infarction is not congruent with the in-hospital mortality measure that is part of the Joint Commission on Accredited Healthcare Organizations (JCAHO) core measures for acute myocardial infarction and an outcome measure that was used in the Premier Hospital Quality Incentive Demonstration project.

OUTLIER PAYMENTS

The rule proposes establishing a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including indirect medical education (IME), disproportionate share hospital (DSH), and new technology payments, plus $25,530. While this is not a particularly sizable increase from the FY 2006 payment threshold of $23,600, we remain very concerned that the threshold is too high. According to our analyses, actual outlier payments for FY 2006 are estimated to be 0.47 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments. CMS spent only 3.8 percent, or $1.15 billion less than set aside in FY 2005, and only 3.5 percent, or $1.3 billion less than the funds withheld in 2004.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2004, in combination with the first quarter of 2005, to the last quarter of 2005, in combination with the first quarter of 2006, to establish an average rate of increase in charges. This results in a 7.57 percent rate of change over one year, or 15.15 percent over two years.

HAP appreciates that CMS is proposing this methodology in an effort to avoid using data from 2003 when charges may have been atypically high. **However, using the proposed charge inflation methodology will only result in an inappropriately high outlier threshold and a real payment cut to hospitals. HAP strongly opposes using this methodology to estimate the outlier threshold.** The AHA conducted a series of analyses to identify a more appropriate methodology. Below is the AHA proposed methodology which HAP encourages CMS consider adopting. The methodology incorporates both *cost* inflation and *charge* inflation. We believe the use of more than one indicator will make the threshold calculation more accurate and reliable.

1. Inflated 2005 charges by 15.71 percent (the inflation factor used by CMS in the proposed rule) and then reduced the charges to costs.
2. Instead of using the cost-to-charge ratios (CCRs) from the CMS Impact File, the CCRs from the March 31, 2006 HCRIS release are used.
3. Take into account the nine-month lag from the end of a cost-reporting period until the FI is able to update the CCR. This is accomplished by projecting forward from the most recent fiscal period in the March 31 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining federal FY 2007 outlier payments.

The cost inflation factor for projecting CCRs was determined from the cost reports of a cohort of 3,253 matched hospitals for periods beginning in federal FYs 2002, 2003, and 2004. All three cost reports were available for each hospital from the recent update of HCRIS. The 2002-2004

aggregate annual rate of increase in the cost per discharge for these hospitals was 5.69 percent[2]. This cost inflation factor and the CMS charge inflation factor of 7.57 percent were used to project CCRs over the time periods described above. The projected CCRs were applied to projected federal FY 2006 charges to simulate the determination of costs for FY 2007 outlier payments. **The estimated fixed-loss amount that would result in 5.1 percent outlier payments under this methodology is $24,000.**

HAP strongly urges CMS to adopt this methodology, which is applicable regardless of what DRG changes are made or not made in FY 2007. We estimate that the fixed-loss threshold necessary to achieve 5.1 percent in FY 2006 should have been set at $21,275 as compared to the $23,600 actually utilized. We believe CMS underspent the funds set aside for outliers by an estimated $3 billion over FYs 2004, 2005, and 2006. **This is a real cut in payments to hospitals that cannot be recouped. If CMS leaves the threshold at $25,530, rather than dropping it to $24,000, we believe that CMS will again significantly underspend by over $300 million.** We urge CMS to adopt our recommended methodology to lower the outlier threshold.

CORE-BASED STATISTICAL AREAS (CBSAS)

In adopting the Core-based Statistical Areas (CBSAs) in FY 2005, a small number of hospitals that were classified as urban in FY 2004 became classified as rural in FY 2005. Because moving from a Metropolitan Statistical Area (MSA) to the rural statewide average would have resulted in a significant decline in these hospitals' wage indexes, CMS implemented a three-year transition period (FYs 2005-2007). **HAP supports the continued transition for these hospitals to give them the opportunity and time to reclassify.**

OCCUPATIONAL MIX ADJUSTMENT

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 requires CMS to collect data every three years on the occupational mix of employees from hospitals subject to the inpatient PPS in order to construct an occupational mix adjustment to the wage index to control for the effect of hospitals' employment choices—such as greater use of registered nurses (RNs) versus licensed practical nurses or certified nurse aides—rather than geographic differences in the costs of labor.

CMS initially stated in the proposed rule that it would again limit the occupational mix adjustment to 10 percent because of concerns regarding the validity of the data and the potential financial impact on hospitals. However, as a result of the decision handed down by the U.S. Court of Appeals for the Second Circuit on April 3 in *Bellevue Hospital Center v. Leavitt*, CMS on May 12 released a proposed rule revising the occupational mix adjustment portion of the FY 2007 inpatient PPS proposed rule. Under the court ruling, CMS must collect new data on the occupational mix of hospital employees and fully adjust the area wage index (AWI) for FY 2007.

Hospitals are required to collect the hours and wages for employees from January 1 through June 30, 2006. Data initially was supposed to be collected by July 31; however, hospitals were

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[2] An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 2,729 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2006 HCRIS update.

required to submit data by June 1 for the first calendar quarter of the year and by August 31 for the second calendar quarter. Data from the first quarter will be used to adjust the FY 2007 AWI, while data for the full six months will be used to adjust the AWI for FYs 2008 and 2009.

Definitions and Covered Employees. In filling out the interim-survey, our members found that the placement of certain employees caused confusion. Examples include surgical technicians, paramedics who are employed by the hospital and usually work in the emergency department, and unit secretaries who are also known as ward clerks. CMS clarified after the proposed rule was released that these employees should be placed in the "all other" category for the interim-collection. Moving forward, CMS should re-evaluate where these employees belong. **However, such changes should not be made to the ongoing collection, as it would necessitate the resubmission of the first calendar quarter's data to ensure that both quarters could be used for FYs 2008 and 2009.** If CMS believes that such changes are warranted, then the hospitals will need notification prior to the release of the final inpatient PPS rule in order to meet the August 31 deadline for submissions.

Cost Centers. We agree with CMS' "bright line" clarification for this collection that only nursing personnel within the cost centers listed should be included in that category for the purposes of consistency. It is significantly less work for hospitals to focus on certain cost centers, and we continue to support this methodology. **We believe that the vast majority of nursing personnel within a hospital fall within these cost centers and do not believe that CMS should include every cost center that may have a few nursing personnel included in it.**

However, CMS should consider refining the list for future collections. Every hospital has a different method for attributing costs to the cost centers, thus there are probably a few cost centers that contain a significant number of nursing personnel for certain hospitals that were not captured for this collection. Given the shortened comment period in combination with the magnitude of the other changes proposed by CMS in the inpatient PPS rule this year, we were unable to extensively research which cost centers CMS should add. We suggest that CMS accept comments on any potential changes to the cost center list before making such changes. **In addition, we believe that additional cost centers should *not* be added to the ongoing collection as it would necessitate the resubmission on the first calendar quarter's data to ensure that both quarters could be used for FYs 2008 and 2009.** If CMS believes that such changes are necessary for the current collection, then hospitals would need notification prior to the release of the final inpatient PPS rule in order to meet the August 31 deadline for submissions.

Non-responsive Hospitals. Because data from all hospitals is needed to construct an accurate national average hourly wage, full participation is critical. There is a general sentiment that hospitals that do not participate should not benefit from the participation of others. However, given the expedited collection and general confusion around the interim-collection, we believe that, to the extent possible, **CMS should substitute data from the previous survey for hospitals that did not turn in their data for the first calendar quarter of 2006.**

However, hospitals will have plenty of notice and time to submit data for the second calendar quarter in August. Thus, moving forward, CMS could consider a methodology that penalizes hospitals that do not participate. We caution CMS not to simply substitute unfavorable data for these hospitals, as it also will impact other area hospitals that conscientiously reported data. CMS could alternatively substitute the national average hourly wage for non-responsive

hospitals in calculating an area's wage index, and then require hospitals that did not turn in data to use something lower than their area's wage index. This would avoid CMS having to create an extensive hospital-specific wage index table and would minimize the effects on the other hospitals in the area. **We urge CMS to construct an application of the occupational mix adjustment that encourages hospitals to report but does not unfairly penalize neighboring hospitals.**

Corrections. **HAP urges CMS to allow hospitals to turn in both calendar quarters of data in August whether for the first time or with corrections.** Again, as this collection has been rushed, the idea is to allow hospitals to improve the data for the FYs 2008 and 2009 adjustment. For hospitals that were previously non-responsive, the submission of the first calendar quarter would remove any penalty, while those that continue to be non-responsive will continue to incur a penalty.

Comment Timeframe. Hospitals must now provide occupational mix data on an extremely expedited timeline, with little or no time for review, and no ability to see how the data will affect their FY07 payment rates. While we understand that CMS is under severe time pressure due to the timing of the court's decision, we do not believe that the 30-day comment period was sufficient, as hospitals were busy during this time trying to meet the new survey deadline and answering requests for information from the FIs. HAP is also concerned that a three-month period may not be sufficient to provide the "robust" data set necessary for valid basis for calculations. In addition, we believe it would be appropriate for CMS to take comments on the calculation after the initial results of the survey are tabulated and posted. The results of the survey could be material. For instance, if the segregation of RNs who are management versus RNs who are staff does not produce a reliable result, CMS might consider consolidating the two for the purposes of the calculation. While CMS might not have time to make such changes for FY 2007, it could entertain comments on the implementation for FYs 2008 and 2009. We are concerned about the collective affect these changes will have on hospital payments and recommends that CMS provide opportunities for review, comment, and adjustment to the occupational mix data (including the ability to appeal or amend bad data), as needed, to the extent allowable under the Court order. **Thus, we urge CMS to publish the occupational mix adjustment changes as an interim-final rule in August with an associated comment period.**

Adverse Effect on Quality/Efficiency Initiatives. As an additional comment, we note that the existing wage index and occupational mix process has the effect of penalizing hospitals that invest in quality/efficiency at the very time that Congress is seeking to improve quality/efficiency under the Medicare program. For example, by utilizing higher levels of Registered Nurses (RNs), hospitals are improving the quality of care provided to seniors, yet they are penalized by the CMS' refusal to recognize these higher above-average costs under the wage index.

The effect of the wage index and occupational mix on these hospitals will reduce or eliminate the annual Medicare inflation increase provided to address the increasing costs these hospitals face. This reduction is not recognized as savings under the Medicare program, but is unfairly redistributed in part to hospitals that arguably have not been as efficient, nor as focused on quality improvement. As a result, these hospitals are placed at a competitive disadvantage that adversely impacts services and limits their capacity to recruit and retain employees and to invest in new technologies.

HOSPITAL REDESIGNATIONS AND CLASSIFICATIONS

Section 508 Reclassifications. Section 508 of the *Medicare Modernization Act* (MMA) provided $900 million over three years for a one-time geographic reclassification opportunity, which expires March 31, 2007. Because the 508 reclassifications expire mid-year and hospitals may not receive Section 508 funding at the same time as any other form of reclassification, CMS has proposed special provisions for accepting or denying partial-year reclassifications for FY 2007.

In FY 2006, CMS stated that individual hospitals reclassified under Section 508 would be allowed to request regular reclassification for the portion of the three-year period that the hospital is not receiving Section 508 funding, or to turn down the Section 508 reclassification for the first half of FY 2007 and receive regular individual reclassification for the full three years.

CMS also stated that Section 508 hospitals that would like to be part of a group reclassification could turn down their 508 reclassification for the first half of FY 2007 and join a group for the full three-year period. Or the hospitals could maintain Section 508 reclassification while the rest of the group gets their "home wage index" for the first half of the year. The entire group then could reclassify together for the rest of the three-year period.

In the proposed rule, CMS clarifies that "home wage index" means that hospitals could receive the wage index they otherwise would have, absent the group reclassification. For some hospitals, this might literally be the wage index for the area in which they are located. For others, this may mean an individual reclassification to another area.

Section 508 hospitals, and those involved in a group reclassification with a Section 508 hospital, would normally have been required to accept or reject reclassification within 45 days of the publication of the proposed rule; however, the complications with the occupational mix adjustment will prevent this. **We appreciate and support CMS' flexibility around the expiration of Section 508 and the reclassification deadlines given the unusual circumstances this year.** Further, HAP supports CMS exploring alternatives to rectify fiscal consequences for those hospitals that qualified under section 508 but did not receive funds.

GEOGRAPHIC RECLASSIFICATIONS

Multi-campus Hospitals. Payment is determined using the wage index value for the MSA in which a campus is located, even though the organization may have other campuses located in different labor market areas. Because multi-campus hospitals submit a single cost report that does not break down wage data by campus, an individual campus historically has been unable to seek reclassification. For FYs 2006-2008, CMS authorized individual campuses to use the average hourly wage data of the entire multi-campus hospital system to seek geographic reclassification to the labor market area in which the other campus(es) are located. CMS also stated in the FY 2006 rule that, in the future, it would continue to consider mechanisms to collect the data necessary for geographic reclassifications that are not unduly burdensome for providers. However, CMS now proposes rescinding this option, as there was only one hospital in the country that was affected by this situation and, after the change in labor market areas in FY 2005, it has subsequently joined an urban county group that is reclassified to the area in which it was previously reclassified using the multi-campus hospital rule.

HAP opposes CMS' proposal to remove this option. While CMS may know of only one hospital at this point, there may be others, and additional hospitals may be affected after the next census collection and subsequent changes in labor market definitions. In addition, the need for this provision has not subsided as CMS suggests. This hospital will need to use either campus-specific or hospital-wide data for its next reclassification, whether group or individual, and lack a method to do so.

CMS suggests that each campus should disaggregate and receive its own provider number. A multi-campus hospital with a single provider number provides certain health and treatment benefits to patients, such as the ability to move among campuses for various aspects of treatment. Each campus may specialize in a particular service (oncology, cardiology, etc.) and patients can move among the campuses with one medical records system, one billing system, and a unified medical staff. Economies of scale reduce costs for the whole system. **Thus, we do not believe it is a realistic or appropriate option to force these campuses to apply for individual provider numbers.**

We recommend that CMS continue to allow multi-campus hospital systems to use the data from all campuses as a proxy for individual campuses to reclassify to an area where another one of the campuses is located given how few hospitals are expected to use this option.

This is a reasonable request as most multi-campus hospital systems likely pay equal or similar wages at each campus. If CMS finds that the situation becomes more prevalent, it could require the manual completion of the campus-specific Schedule S-3 for those hospitals that do not have the appropriate individual campus data. However, if CMS moves to a campus-specific S-3, CMS still needs to extend the current special rule for five years until the new campus-specific data is useable for an application.

Urban Group Reclassifications. HAP supports CMS' proposal to allow hospitals located in counties that are in the same core-based statistical area (CBSA) as the county in which they seek redesignation to be considered to have met the proximity requirement. **Given that CBSAs are actually more refined classifications than Combined-statistical Areas, we believe that the inclusion of CBSAs in the proximity criteria would be consistent with CMS' policy goals and protect hospitals from unintended consequences.**

Critical Access Hospitals in Lugar Counties. As a result of changes in the labor market area definitions made in response to the results of the 2000 census, counties in which a number of Critical Access Hospitals (CAHs) are located became "treated" as urban instead of rural under the inpatient PPS because of a statutory provision modifying the status of rural counties with certain commuting patterns to metropolitan areas. In its FY 2005 final rule, CMS interpreted this provision as applying to CAHs located in these counties (Lugar counties) and allowed these facilities a grace period to seek reclassification as rural in order to retain their CAH status.

While accommodating CAHs in this manner, the agency also took the position that any CAH being reclassified would no longer be eligible for pass-through payments for the services of certified registered nurse anesthetists (CRNAs). Its reasoning was that the facility was no longer "located in a rural area (as defined for purposes of section 1886(d) of the Social Security Act)" as the pass-through statute requires, but were only reclassified as rural.

In response to comments received on the FY 2006 proposed rule, CMS announced a policy change in the final rule for FY 2006 stating that Lugar county designation would not affect a CAH's rural status because the statutory provision creating such counties only applies to hospitals paid under the inpatient PPS (CAHs are paid under a separate, cost-based system). This policy change had the effect of eliminating the need for these CAHs to seek either geographic reclassification or a waiver of the Lugar statute (which CMS has maintained it has no authority to do). **In effect, under this new reading of the law, the provision creating Lugar counties does not apply *at all* for purposes of CAH eligibility.**

Despite this policy change, CMS continues to maintain that a CAH located in a newly-designated Lugar county cannot qualify for CRNA pass-through payments. This position is at odds with the agency's view that *it is geographic reclassification that renders a CAH ineligible for such payments*—since, under CMS' revised policy, a CAH located in such a county need not seek geographic reclassification to be a CAH. Apparently, it is CMS' view that these CAHs can never qualify for CRNA pass-through payments, whether they have sought reclassification (under the old policy) or not (under the new policy). **We believe that all CAHs located in a newly-designated Lugar county should receive pass-through payments, regardless of whether they sought reclassification, and urge CMS to revise its regulations accordingly.**

WAGE INDEX BUDGET NEUTRALITY

CMS eliminates the CAH data from the wage index file it uses to compute the national average hourly wage (NAHW). For FY 2007, 1,191 CAHs representing approximately 24 percent of all inpatient PPS hospitals (as of FY 2000) – 55 percent of all rural hospitals in FY 2000 – have been eliminated from the file. Because CAHs have lower average hourly wages (AHWs) than the average PPS hospital, the elimination of this data results in an overstated NAHW. While the NAHW has been increasing, the systematic withdrawal of low-wage hospitals has artificially inflated the NAHW to some extent. This artificial increase is included in the negative budget neutrality adjustment that consequently reduces payment, resulting in the national inpatient PPS operating payments being understated by an estimated $1.52 billion over five years (2003-2007). **Thus, we believe that CMS should apply a positive budget neutrality adjustment in FY 2007 to compensate for the underpayments.** The understatement increases each year as more hospitals become CAHs and more data are eliminated from the wage index data. However, we believe that this could be a one-time adjustment as we expect very few hospitals to convert to CAH status now that the necessary provider designation is no longer an option.

LOW-VOLUME HOSPITAL PAYMENT ADJUSTMENT

Section 406 of the MMA created a payment adjustment under the inpatient PPS to account for the higher costs per case of low-volume hospitals. The law defined eligible hospitals as those located more than 25 miles from another facility with fewer than 800 total discharges annually. The rule proposes to maintain a 25 percent increase, the maximum allowable, in payments to hospitals with fewer than 200 discharges. For those hospitals that have between 200 and 800 discharges, CMS proposes to maintain its current policy, applying no payment increase. Only two hospitals will receive this adjustment in FY 2007 according to CMS estimates. **HAP is concerned that CMS is ignoring congressional intent and denying a group of hospitals—those with more than 200 discharges but fewer than 800 discharges—access to this necessary payment increase.**

SCH/MDH Changes in Qualification Status

The proposed rule would require an approved sole community hospital (SCH) or Medicare dependent hospital (MDH) to notify the appropriate CMS Regional Office of any change affecting its classification as such. To date, it has been the FIs responsibility to evaluate hospitals' continuing qualification for SCH or MDH status. CMS expects the hospital to now self-disclose any material changes in circumstances or potentially face a retroactive cancellation of their designation once an FI discovers its ineligibility.

This appears to be an inappropriate shift of the burden from the FIs to hospitals. For instance, hospitals are neither involved in, nor have any control over, the building of new roads or new hospitals and thus should not be accountable to report such changes. It also would be very difficult for hospitals to know when and for how long there were prolonged severe weather conditions that closed area roads, or to note changes to posted speed limits and traffic patterns. In addition, some of the qualifying criteria, such as inpatient admissions at other regional hospitals, would be hard to monitor as the hospitals do not have this sort of data on their competitors. Requiring hospitals to constantly monitor whether they continue to meet these requirements would impose a tremendous and unreasonable administrative burden on hospitals. **HAP recommends that this function remain a responsibility of the FIs, who are in a better position to monitor these circumstances. If CMS requires hospitals to report changes in circumstances, then the specific types of situations should be noted and should only include aspects of their operation that are within their control (e.g., number of beds).**

CMS' proposal to retroactively withdraw SCH or MDH status if a hospital does not appropriately self-report a change in circumstances could be financially devastating. CMS should at minimum give consideration to whether the hospital had knowledge of the disqualifying circumstance. Hospitals should not have to repay CMS based on the difference between the inpatient PPS or outpatient PPS payment and the SCH or MDH payment when they did not know that they no longer qualified for the program. Instead CMS should develop a prospective process for withdrawing the hospitals' SCH or MDH status. We believe that a 30-day timetable for losing SCH/MDH status is unrealistic given the financial implications of such a change and the inability for a hospital to plan for this outcome. **CMS should re-evaluate the proposed timetable for canceling SCH/MDH status when a hospital is found to be disqualified or self-reports disqualification and consider revoking the hospitals' status as of the following cost-reporting period.**

SCH/MDH Volume Decrease Adjustment

An SCH or MDH may apply for special payments if it experiences a decrease of 5 percent or more in its total number of inpatient discharges that was out of its control from one cost-reporting period to another. If the hospital qualifies, it must demonstrate that it took measures to scale back its nursing force commensurately. The adjustment is intended to cover the fixed costs that the hospital is unable to reduce in the year following the volume decrease. CMS believes that only "core staff and services" should be covered by these special payments. To date, CMS has used the AHA's HAS/Monitrend Data Book to compare the hospital's staffing to other similar hospitals in the area to determine if the hospital is staffing its routine and intensive care units appropriately. However, the Data Book has not been updated since 1993. CMS has been using the 1989 publication. Thus, CMS proposes using the occupational mix adjustment data

currently being collected for wage index purposes to calculate nursing hours per inpatient day for a hospital in question and local peer hospitals.

The occupational mix adjustment was only partially implemented in its first three years, primarily due to the questionable data and results. The current collection, which is occurring again under rushed circumstances, may also result in questionable data. **We do not believe that it is wise to assume that the occupational mix adjustment data will be appropriate for this use. HAP believes that the data within the AHA annual survey should be sufficient for CMS to determine the nursing levels per patient day.**

RURAL REFERRAL CENTERS

If a hospital wants to become a Rural Referral Center (RRC) but does not have 275 or more beds, it must meet two mandatory alternative criteria plus one of three additional criteria. The proposed rule would update the alternative criteria for RRC designation in FY 2007.

Until recently, the median case-mix index values were very stable. The chart below illustrates the volatility over the past few years in the values for two regions:

Region 7 West South Central	
FY 2005	1.1371
FY 2006	1.3532
FY 2007	1.2445
Region 6 West North Central	
FY 2005	1.0855
FY 2006	1.2252
FY 2007	1.2856

While it is not clear why this is occurring, it does suggest a possible methodological problem. **Thus, we recommend that CMS undertake additional analyses to determine the cause of the recent fluctuations.** This is particularly important given the possible disruption to case-mix patterns as a result of a new patient classification system such as the CS-DRG proposal.

CRITICAL ACCESS HOSPITALS (CAHS)

On November 14, 2005, CMS issued interpretive guidelines on the relocation of CAHs as a follow-up to the FY 2006 inpatient PPS final rule that established the "75% test"—serving 75 percent of the same population, providing 75 percent of the same services and employing 75 percent of the same staff—for necessary provider CAHs. The guidelines not only extended the 75% test to *all* CAHs, but it also altered the definitions of "mountainous terrain" and "secondary road."

We believe that these guidelines go well beyond the regulations included in the FY 2006 rule that provoked numerous critical responses from individual CAHs, associations and congressional representatives. The "mountainous terrain" and "secondary road" definitions are overly prescriptive and the 75% test does not provide reasonable flexibility based on natural variation in demographics, patient needs distribution patterns, normal employee and board attrition, and necessary changes in services to meet community needs. **Rural hospitals that move a few miles are clearly the same providers serving the same communities.**

Many CAHs are planning to rebuild in the near future to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or making other essential upgrades. Facilities expect to relocate when they rebuild for a multitude of reasons: to be closer to a highway, to connect to municipal water and sewer, because of seismic safety concerns, or other similar concerns. **Such improvements will undoubtedly result in higher quality care, better patient outcomes and more efficient service, yet CMS' guidelines discourage these improvements.**

CMS' guidelines will not only impose an unnecessary burden on CAHs, but will preclude many of them from securing financing for needed capital improvements. The hospitals themselves, their hospital districts and their lenders cannot risk investing in a hospital that will be unsure of its status until a year after moving. **CMS should create a preliminary approval process to give assurances to those involved in the project that the CAH relocation will be approved if it meets the assertions made in the attestation submitted to CMS.**

Again this year, almost 60 congressional representatives signed a letter to CMS showing their support for their CAHs and urging changes to these guidelines. We agree with their recommendations and reiterate our suggestion from last year that a safe harbor be established for hospitals relocating within five miles of their existing locations. These providers are not only clearly serving the same communities, but trying to improve the quality of and access to needed health care services. A safe harbor will reduce the administrative burden on not only the hospitals, but CMS and the state survey agencies as well. **We urge CMS to create a safe harbor for CAHs moving a short distance and to make significant changes to these guidelines based on the feedback from CAHs around the nation as detailed in our letter under separate cover to Thomas Hamilton, director of the survey and certification group.**

GRADUATE MEDICAL EDUCATION (GME) PAYMENTS

Exclusion of Didactic Training. The proposed rule states that resident training that occurs at non-hospital sites must be related to patient care if a hospital wishes to count that time for direct medical education (DGME) and indirect medical education (IME) payment purposes. Resident time spent in didactic activities that often occur in associated medical schools—such as educational conferences, journal clubs and seminars—would specifically be excluded. CMS noted that its statement in a previous letter on this topic "implying that didactic time spent in non-hospital settings could be counted for direct GME and IME ... was inaccurate." CMS also noted that time spent in these activities could be counted for DGME purposes if they occur in a hospital; however, the counting prohibition applies for IME payments regardless of where the educational activity occurs.

We strongly urge CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare DGME and IME payments. The stated rationale for the exclusion of this time is that it not "related to patient care." This position is in stark contrast to CMS' position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted

broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty."[3]

We strongly agree with CMS' 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. In addition, it would be very difficult to separate out time spent at these activities. **We urge CMS to withdraw this change in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.**

EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA)

Definition of "Labor." **HAP supports CMS' proposal to modify the definition of "labor" at 489.24(b) to allow a certified nurse-midwife or other qualified medical personnel operating under their scope of practice, as defined in hospital medical staff bylaws and in state law, to certify that a woman is in false labor.** This change recognizes that licensure and scope of practice should remain under the purview of state law and regulation. Further, this change provides hospitals with the staffing flexibility needed to maintain access to and the efficiency of vital obstetrical services, particularly in hospitals located in areas of the country that may find it difficult to attract and retain physicians, such as rural areas.

Hospitals without Dedicated Emergency Departments (ED). Under the proposed rule, a hospital with "specialized capability" is required to accept appropriate transfers under EMTALA regardless of whether it has a dedicated ED. **Guidance is still needed on the definition of specialized capability.** The EMTALA technical advisory group (TAG) has the ability to make recommendations for clarifying guidance, and we look forward to working with its members on this topic. In addition to questions related to the availability of on-call physicians and inpatient psychiatric resources, this proposed regulation calls into question application to inpatient rehabilitation facilities and long-term acute care hospitals.

HAP agrees that a physician-owned, limited-service hospital should be treated as a hospital "with specialized capability or facilities" under EMTALA without regard to whether it has an ED. However, in the DRA-mandated HHS interim report to Congress on its development of a strategic plan regarding physician investment in specialty hospitals, the Secretary suggested that this interpretation of EMTALA "may result in an increase in the number of specialty hospitals accepting transfers of emergency patients on nights and weekends." (CMS uses "specialty" to mean the hospitals covered under Congress's moratorium, i.e., physician-owned, limited-service hospitals providing primarily cardiac, surgical or orthopedic services.) **HAP believes it is unlikely that this will result in improved access for patients to the specialty care they need.**

It is important to separate the capabilities of the practicing physicians from the capabilities of the facility in which they are practicing. While the physician expertise housed in the physician-owned, limited-service facility could be capable of meeting the needs of community hospital patients, the facility is seldom designed or operated in a manner to support this level of practice. Although physician-owned, limited-service hospitals hold themselves out as "hospitals," many of these facilities actually have a range of capabilities more similar to a hospital department or

[3] September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins.

ambulatory surgical center. These hospitals often do not have emergency capabilities, as they are geared toward elective cases of minor severity. Their capabilities are typically limited to a single major diagnostic category, and they staff for minimal inpatient capacity. Many of these facilities minimize resource consumption by being almost a Monday through Friday operation. For these reasons, it generally would not be in the best interests of community hospital patients to be transferred to these facilities.

At the same time, many physician-owned, limited-service hospitals have withdrawn specialist services from the community at-large. As these physicians maintain an increasing amount of their practice at these hospitals or other sites outside the community hospital (e.g., ambulatory surgical centers), they are much less willing to accept on-call responsibility for the broader community's emergency needs. While withdrawing specialist services from on-call coverage, these same physician-owned, limited-service hospitals presume to rely on the community hospital for back-up in the event of complications requiring around-the-clock access to emergency care and inpatient admission to the community hospital. With the change in physician practice patterns and the increased number of physicians requesting only courtesy admitting privileges at community hospitals, relying only on the professional obligations attached to admitting privileges is not sufficient to assure appropriate transfer arrangements and the availability of physicians to provide emergency specialty capacity. **Every physician-owned, limited-service hospital that relies on the community's emergency services capacity should be obligated to support it by assuring on-call coverage for the community's hospitals emergency departments.**

In addition, this policy does not address the problem of patients at physician-owned, limited service hospitals who suffer from complications appearing in a hospital ED with no warning call, no medical history, no operative report, no information on the anesthesia used and, often, no ability to reach the treating surgeon for consultation. **Physician-owned, limited-service hospitals should be required to have transfer agreements with the community hospitals they plan to rely on in the event that they do not have the capacity to treat a particular patient.**

Specifically, HAP recommends the following:

- **A physician-owned, limited-service hospital should be required to have a pre-existing transfer agreement with the community hospital(s) it intends to rely on for emergency back-up services.**

- **The Secretary should establish the terms that must be addressed by a transfer agreement, including:**

  - **Procedures for an appropriate transfer for patients not covered under EMTALA** (e.g., inpatient or outpatient whose condition develops into an emergency beyond the capability of the limited-service hospital and consequently needs to be transferred to a full-service hospital);
  - **Continuity of care** (e.g., telephone consultation with the receiving hospital and physician, sending the patient's medical records along when transferred, etc.); and
  - **Support for maintaining full-time emergency capacity at the community hospital, including on-call coverage** (e.g., physician-owned, limited-service hospital physicians serve in on-call panels at the community hospital, or the physician-owned, limited-

service hospital provides financial support to the community hospital to maintain on-call coverage).

NEW TECHNOLOGY

Section 503 of the MMA provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. However, CMS continues to resist approval of new technologies and considers only a few technologies a year for add-on payments. **HAP is disappointed that CMS has not increased the marginal payment rate to 80 percent rather than 50 percent, consistent with the outlier payment methodology, as previously was requested by the AHA.**

Moreover, we are concerned about CMS' ability to implement add-on payments for new services and technologies in the near future. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to as ICD-10) were developed as replacement classification systems.

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the MMA, recommended that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology, as required under the *Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000.*

To date, despite these recommendations, as well as the recommendations of several federal health care agencies and offices and health care trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that absent a switch to ICD-10 soon, there will be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. In addition, failure to recognize this looming problem will only impede the efforts to achieve President Bush's goal for an electronic health record by 2014.

At the April 2005 ICD-9-CM Coordination and Maintenance (C&M) committee meeting, there were many impassioned discussions on the need to start limiting the creation of new procedure codes in order to allow the classification system to last at least two more years. ICD-9-CM procedure code categories 00 and 17 were created to capture a diverse group of procedures and interventions affecting all body systems. The establishment of these code categories represented a deviation from the normal structure of ICD-9-CM and a stopgap measure to accommodate new technology when no other slots in the corresponding body system chapters (e.g. musculosketal system, circulatory system, etc.) were available. The plan was to use codes in chapter 00 first and then begin populating chapter 17.

Category 00 is now full, and the C&M committee is entertaining proposals for codes in category 17. At the April C&M meeting a proposal was presented that would in effect leave only 80 codes available in this category. Many of the specific body system chapters are already filled (e.g., cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in one-and-a-half years. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule.

HAP recommends that the Secretary undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS expeditiously. HHS should take the necessary steps to avert this crisis and avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than respond to a crisis that will likely result in unreasonable implementation timeframes. It is imperative that the rulemaking process start immediately.

OTHER FUTURE CONCEPTS

TRANSPARENCY OF HEALTH CARE INFORMATION

The proposed rule includes the introduction of a proposed initiative to expand the public availability of consumer information on health care quality and pricing. HHS intends to identify several regions in the United States with high health care costs where there is significant interest in reducing those costs and improving health care quality.

Significant progress has been made in making quality information more transparent. The AHA, the Federation of American Hospitals and the Association of American Medical Colleges partnered with CMS and others to form the Hospital Quality Alliance (HQA). The work of the HQA has led to the voluntary reporting and sharing with the public of 21 quality measures on the *Hospital Compare* Web site, and more measures of hospital quality and patient satisfaction are planned for the future. This effort has been tremendously successful, with nearly all inpatient PPS hospitals voluntarily reporting quality information. **Efforts to further expand public availability of hospital quality information must continue to be pursued through the HQA.**

While progress has been made regarding quality transparency, similar information on hospital pricing is less accessible. In the proposed rule, CMS details four options for providing pricing information to health care consumers, including:

- Publishing a list of hospital charges, either for every region of the country or selected regions of the country;
- Publishing the rates that Medicare actually pays to a particular hospital for every DRG, or for selected DRGs, which could be adjusted to account for the hospital's labor market area, teaching hospital status and DSH status;
- Establishing conditions of participation for hospitals that relate to the posting of prices and/or the posting of their policies regarding discounts or other assistance for uninsured patients; and
- Posting total Medicare payments for an episode of care. Under this proposal, CMS could include the costs for an inpatient hospital stay, physician payments (including the surgeon and the anesthesiologist), and payments for post-acute care services such as those

provided in an inpatient rehabilitation facility, skilled nursing facility or LTCH for a certain service (such as hip replacement).

People deserve meaningful information about the price of their hospital care. Hospitals are committed to sharing information that will help people make important decisions about their health care. Sharing pricing information, however, is more challenging because hospital care is unique. Hospital prices can vary based on patient needs and the services they use; prices reflect the added costs of hospitals' public service role—like fire houses and police stations—serving the essential health care needs of a community 24 hours a day, seven days a week; and most hospitals cannot yet provide prices that reflect important information from other key players like the price of physician care while in the hospital or how much of the bill a patient's insurance company may cover. But more can, and should, be done to share hospital pricing information with consumers.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge hospitals, and CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;
- Making information easy for consumers to access;
- Using common definitions and language to describe pricing information for consumers;
- Explaining to consumers how and why the price of their care can vary; and
- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

The AHA recently released a position statement on hospital pricing transparency outlining steps to be taken to improve the pricing information available to health care consumers which HAP supports. The following four steps provide a recommended roadmap for pricing transparency.

1) **A federal requirement for states, working with state hospital associations, to expand existing efforts to make hospital charge information available to consumers.**

   - Thirty-two states already have statutes requiring hospitals to report pricing information that is made available to the public either by posting to a hospital, hospital association or government Web site, issued in a government or hospital association report, or made available to consumers upon request; five additional states voluntarily do so.

   - State efforts on price transparency vary, from making individual hospitals' master list of charges available to the public (e.g., California), to making pricing information on frequent hospital services available to the public (e.g., Missouri, Florida, Nevada, North Carolina), to making information on all inpatient services available to the public (e.g., Colorado, Kentucky, Oregon, Pennsylvania, Wisconsin).

2) **A federal requirement for states, working with insurers, to make available in advance of medical visits, information about an enrollee's expected out-of-pocket costs.**

   - This information is especially important to the majority of consumers who already have some type of health insurance coverage. Their likely interest is in knowing the amount

for which they personally are financially responsible. This information is provided today to consumers by their insurance company—it is called an "explanation of benefits, or EOB—but is only given after care is provided. To help inform consumers in advance of their out-of-pocket obligations, insurers could provide an "advance EOB." This information could be shared with an insured individual by phone or electronically through an insurer's Web site. Aetna is currently piloting a project like this for physician services in Cincinnati.

3) **A federal-led research effort to better understand what type of pricing information consumers want and would use in their health care decision-making.**

We have learned much based on research about what kind of information consumers want about the quality of their health care. But we know less about what consumers may want to know about pricing information. Consumers need different types of price information, depending on whether and how they are insured. The following illustrates different consumer needs:

- **Traditional Insurance.** Because traditional insurance typically covers nearly all of the cost of hospital care, people with this type of coverage are likely to want information about what their personal out-of-pocket cost would be if they receive care at one hospital versus another.

- **Health Maintenance Organization (HMO) Insurance.** People who have HMO coverage will have even more specific price information needs. They have agreed, in advance, to adhere to certain limits on their choice of physician or hospital in exchange for broad-based coverage of their health care needs. A person with HMO coverage typically faces no additional cost for care beyond their premium and applicable deductibles and copayments, but must agree to use physicians and hospitals that are participating in that HMO plan. These individuals likely have little, if any need for specific price information.

- **High-Deductible or Health Savings Account (HSA) Insurance.** People with HSAs have more interest than a typically insured person in price information. These types of plans are designed to make consumers more price-sensitive and to encourage consumers to be prudent "shoppers" for the care they need. A typical plan of this type has a deductible of $2,500. However, consumers with HSA coverage are likely to be more interested in price information for physician and ambulatory care than for inpatient hospital care for several reasons:

  - Many patients admitted to the hospital were first seen on an emergency basis in the hospital emergency department. These are not price-shopping patients, but patients who found themselves in need of emergent care and either came or were brought to the nearest hospital emergency department.
  - For patients admitted to the hospital for a scheduled or elective procedure, inpatient hospital price information may be less important because most, if not all, hospital admissions result in a cost that exceeds the typical HSA deductible of $2,500, and therefore, are covered by most HSA plans.
  - People with HSA coverage may be most interested in comparing prices and shopping for care to be delivered that leads up to meeting their deductible (typically $2,500). People with this type of coverage may be most interested in

prices for physician office visits and other ambulatory care for which they are likely to be responsible for paying the full cost.

- **Uninsured Individuals of Limited Means.** People without insurance who have limited means for paying for the health care services they have received need to know how much of their hospital or physician bill they may be responsible for. In the case of hospital care, the information they need must be provided directly by the hospital, after the hospital can ascertain whether a patient may qualify for state insurance programs of which they were unaware, free care provided by the hospital, or other financial assistance.

4) A hospital-led effort to create consumer-friendly pricing "language"—common terms, definitions and explanations to help consumers better understand the information provided.

More can be done to explain pricing information to consumers clearly and consistently. Hospitals will lead an effort to create common terms, definitions and explanations of complex pricing information. This will include sharing innovative and understandable ways for displaying pricing information for use by consumers.

The four points of this roadmap include an appropriate role for HHS, which should provide incentives to the states to improve transparency at the state and local level. HHS, through the Agency for Healthcare Research and Quality (AHRQ), is in the best position to complete research on what consumers want and would use in purchasing health care services.

HOSPITAL VALUE-BASED PURCHASING

Plan for Implementing Hospital Value-Based Purchasing in FY 2009 – In the proposed rule, CMS describes several of its efforts over the past several years to improve the quality and efficiency of care delivered to Medicare beneficiaries in America's hospitals, including CMS' participation in the Hospital Quality Alliance as a strategy to encourage hospital accountability by making comparative information about hospital performance publicly available and the testing of innovative approaches to improving quality through pilot project such as the Premier Hospital Quality Incentive Demonstration. Pennsylvania hospitals have actively participated in both projects.

CMS also notes in the proposed rule that "all providers to which a specific Medicare payment system applies receive the same amount for a service, regardless of its quality or efficiency. As a result, Medicare's payment systems can direct more resources to hospitals that deliver care that is not of the highest quality or include unnecessary services (duplicative tests and services or services to treat avoidable complications)." Consequently, CMS has indicated that it is examining the concept of "value-based purchasing," which may use a range of incentives to achieve identified quality and efficiency goals as a means of promoting better quality of care and more effective resource use in the Medicare payment systems. And, the DRA of 2005 has directed CMS to develop a plan to implement value-based purchasing beginning with FY 2009.

CMS is requesting public comment on the various components that the plan must cover, including measure development and refinement; data infrastructure; incentive methodology (structure of the incentive; level of incentive required; source of the incentives; form of the

incentives; timing of incentives; and development of composite scores); and public reporting. Without a specific proposal to react to, HAP has carefully reviewed the construct of the Premier Hospital Quality Incentive Demonstration pilot project and the recommendations made by the Medicare Payment Advisory Committee (MedPAC) in developing some initial comments to share with CMS.

Some of our initial thoughts are shared below.

- As already mentioned, HAP believes that there needs to be ongoing discussion with the partners in the Hospital Quality Alliance with regard to which measures should be added and which measures should be deleted from inclusion in any pay-for-performance measurement system. Although the National Quality Forum has endorsed specific measures, there may be strong preferences to include certain measures in a value-based purchasing system over others. HAP strongly believes that the measures selected should be those that hospitals have the capacity to improve.
- It is clear in the CMS proposed rule, the MedPAC report, and the President's FY 2007 Budget that new monies will not be invested in the Medicare program to be used as a quality incentive payment pool. Rather, it appears that a small proportion of Medicare hospital payments (1-2 percent of payments) will be set aside to fund a quality incentive payment pool in order to maintain budget-neutrality. CMS has indicated that its ability to measure quality improves, the amount of money set aside to reward quality performance should increase significantly. Further, MedPAC has recommended that any quality incentive program reward hospitals for improvement and attaining/exceeding certain benchmarks. HAP supports the concept of rewarding hospitals both for improvements and attaining/exceeding certain benchmarks. HAP understands the effort that needs to be invested by hospitals to make quality improvements in processes of care and in ensuring that those improvements are sustained at the highest levels. However, HAP is not convinced that setting aside 1-2 percent of Medicare payments is sufficient to make meaningful awards to hospitals for making improvements and attaining certain benchmarks. For instance, while there were significant improvements made by those hospitals that participated in the Premier Hospital Quality Incentive Demonstration project, only those hospitals with the best quality scores (top 2 deciles) received a bonus incentive payment.
- Pennsylvania hospitals strongly support the development of a composite score for a particular disease category or measure set. HAP and Pennsylvania hospitals believe that composite scoring may assist in improving consumer understanding of the processes/dimensions of care as well as assist hospitals in communicating with its clinical teams. In the proposed rule, CMS describes the "opportunity model" composite score methodology employed in the Premier Hospital Quality Incentive Demonstration project and the "appropriate care measure" composite scoring currently being used by QIOs in the 8th scope of work. Of the two methods described, HAP strongly prefers the use of the "opportunity model" used in the Premier Hospital Quality Incentive Demonstration project to the "appropriate care measure" concept. HAP believes that the "opportunity model" provides the flexibility needed to accommodate more individual process and/or outcome measures and the ability to determine whether and how to assign more weight to various measures. CMS notes that there are other proprietary composite measures, including those used by Solucient, Healthgrades, and CareScience. HAP would be interested in responding to other composite scoring methodologies under consideration by CMS, including proprietary methodologies. Additionally, HAP supports the

combination of measures within a particular disease category but is not sure that it could support rolling up disparate dimensions of care into an overall composite score without having a specific proposal(s) to react to in this regard.

- Should CMS choose to implement a program that ranks hospitals in some sort of descending order as was the case in the Premier Hospital Quality Incentive Demonstration project to determine which hospitals will receive bonus incentive payments, it will be extremely critical that CMS have an infrastructure in place that allows hospitals to compare their performance against other hospitals on an ongoing basis. HAP believes that it would be extremely important to engage in discussions with performance measurement vendors to determine collaboratively how quick performance feedback to hospitals can be accomplished.

RECOMMENDATIONS

HAP believes that it is essential that CMS work with its Hospital Quality Alliance partners in developing quality incentive proposals that could be shared in the near future with the hospital community for comment given the short-time frame that has been mandated by Congress to begin a Medicare value-based hospital purchasing program. HAP also believes that this should be an iterative process whereby the hospital community has sufficient opportunity to comment on a proposal(s) and modifications to the proposal(s) based on the comments received. This is a process that will need to be repeated several times to prepare the hospital community for the value-based purchasing program and obtain consensus with regards to the value-based hospital purchasing program that CMS selects to implement. HAP recommends that CMS consider implementing a process similar to that used jointly by CMS and the Agency for Healthcare Research and Quality (AHRQ) in shaping the HCAHPS® perception of care survey/ survey methodology to develop the Medicare value-based purchasing program for hospitals. This is a process that involved multiple opportunities for public comment.

HEALTH INFORMATION TECHNOLOGY (IT)

The proposed rule states that it "supports the adoption of health IT as a normal cost of doing business to ensure patients receive high quality care." It also notes that the quality and efficiency benefits of health IT may provide a policy rationale for promoting the use of health IT through the Medicare program. Consequently, CMS asks for comments on:

- Its statutory authority to encourage adoption and use of IT;
- The appropriate role of IT in any value-based purchasing program; and
- The desirability of including use of certified health IT in hospital conditions of participation.

HAP believes that health IT is a very important tool for improving the safety and quality of health care, and Pennsylvania hospitals are committed to adopting IT as part of their quality improvement strategies. They also view IT as a public good that requires a shared investment between the providers and purchasers of care.

Health IT is very costly, requiring both upfront and ongoing spending. A 2005 AHA survey of hospitals and health systems found that the median amount hospitals invested on health IT in one year was more than $700,000, 15 percent of total capital expenses. Hospitals spent even greater

amounts – a median of $1.7 million or 2 percent of all operating expenses—on operating costs. Survey respondents identified the upfront and ongoing costs of IT as the greatest barriers to further adoption. The survey also found that hospitals with negative margins and those with lower revenues use less IT.[4]

The proposed rule highlights the anticipated benefits of health IT as laid out by the RAND Corporation. However, it overlooks another of the study's major findings—that the financial benefits of IT investments accrue more to the payers and purchasers of care than the hospitals and health systems that pay for them.[5]

Simply put, hospitals have not seen financial returns greater than the costs of implementing clinical IT systems, particularly in the short term. They adopt clinical IT because it is the right thing to do for improving patient safety and quality of care, not because it saves them money. Thus, while IT may be a "normal cost of doing business," it systematically raises those costs. **Given that they reap many of the financial benefits of IT, HAP believes that the payers and purchasers of care should share in the costs of IT.**

Finally, we learned through the HIPAA process that efficient health information exchange requires all parties to upgrade their systems and work from a common set of standards. As we moved toward implementation of health IT in hospitals, payers—including the federal government—must modify their own systems to accept electronic data.

Statutory Authority. The broad question of whether CMS has statutory authority to encourage adoption and use of health IT will depend on the specific mechanisms it selects. For example, CMS has some authority to pursue demonstration projects. However, more systematic approaches, such as value-based purchasing or payment adjustments, would require legislative action.

Value-based Purchasing. HAP believes that any value-based purchasing program should not be punitive. **With regard to IT, only programs that add funds to the inpatient PPS should be pursued because IT is costly, requiring both upfront and ongoing expenditures.** Decreasing payments to those that have not been able to afford IT further limits their ability to invest. A budget-neutral approach also ignores the reality that health IT systematically increases hospitals' costs.

HAP also believes that value-based purchasing programs should build off the consensus measures endorsed by the broad spectrum of organizations—including CMS—that participate in the HQA. In general, the HQA favors measures that address quality outcomes, rather than the tools used to get there.

Health IT can play a role in reducing the burden of quality reporting. Presently, electronic health records (EHRs) and other clinical IT systems do not automatically generate quality measures. Most hospitals still require special calculations—including expensive manual chart abstraction and use of third-party contractors—to submit quality data. CMS could advance the quality

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[4] "Forward Momentum: Hospital Use of Information Technology." Washington, DC: AHA (2005).
[5] R. Hillestad, J. Bigelow, A. Bower, F. Girosi, R. Meili, R. Scoville, and R. Taylor. "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs," *Health Affairs*, September 1, 2005; 24(5): 1103 - 1117.

agenda by investing in the development of algorithms for the calculation of the quality measures it wants reported from EHRs and encouraging vendors to include them in their products.

Rather than including health IT in a value-based purchasing program, **CMS could support adoption of health IT through a payment adjustment funded with new money.** For example, it could increase payments to hospitals that use health IT that improves the safety and quality of care by 1 percent. This kind of payment adjustment represents Medicare's share of the necessary investment to achieve this goal and would recognize the greater costs of a "wired" health care system. HAP supports and will pursue legislation in collaboration with the AHA authorizing such a payment adjustment. Other mechanisms, such as loan guarantees and grant funds, are needed to help hospitals finance the upfront costs of implementing health IT.

Conditions of Participation. HAP does not believes that **CMS should include health IT in the Medicare conditions of participation (COP) for hospitals.** The COPs address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, the commercial health IT applications available do not always meet hospitals' needs. The evidence on health IT does not yet support this level of requirement and would amount to an unfunded mandate. A recent report supported by the AHRQ found that the existing research on the quality benefits of health IT is limited to a handful of leadership institutions that generally developed their own systems. And, while promising, the results are not yet generalizable to the average community hospital using the vendor systems currently on the market.[6]

While HAP appreciates the efforts of the Certification Commission on Health Information Technology (CCHIT) to provide the market with better confidence in vendor product, we do not believe those efforts are sufficiently advanced to warrant inclusion in any adoption incentives CMS might pursue. CCHIT is only at the beginning stages of looking into certification of hospital inpatient products. CCHIT's work on ambulatory products is more advanced but, while it shows promise, has not yet proven itself in the marketplace.

Reducing Hospital Payment for Preventable Complications – Under the Medicare diagnosis-related group (DRG) based inpatient prospective payment system (IPPS), payments to hospitals can increase when a post-admission complication occurs. Because of the current design of the current DRG system, hospitals with low complication rates could be viewed as being financially penalized because they receive less reimbursement for providing quality care.

Most pay-for-performance systems provide retrospective financial bonuses to hospitals if specific process and/or outcome standards are met. As another aspect of its value-based purchasing plan, Congress has determined that hospitals should not receive higher amounts of reimbursement when post-admission complications occur. Congress, through the DRA, (1) directs CMS to identify at least two conditions that are high cost/high volume or both that result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis code that reasonably could have been prevented though the application of evidence-based guidelines by October 1, 2007; (2) requires hospitals submit the secondary

[6] "Costs and Benefits of Health Information Technology." Agency for Healthcare Research and Quality Publication No. 06-E006 (April 2006).

diagnoses that are present at admission on inpatient claims for discharges on or after October 1, 2007; and (3) obligates CMS to lower reimbursement to hospitals for discharges on or after October 1, 2008, for cases in which one of the selected conditions was not present on admission. CMS is requesting input about which conditions and which evidence-based guidelines should be selected.

It would appear that there is a strong indication from Congress that either one or both conditions be hospital-acquired infections and that hospitals not receive additional payment for treatment of these infections that could have likely been prevented if the hospital had implemented evidence-based guidelines. Pennsylvania hospitals have been required to report hospital-acquired infections since January 2004 to the Pennsylvania Health Care Cost Containment Council (PHC4). HAP would like to share with CMS what HAP has learned from Pennsylvania hospital experiences with hospital-acquired infection (HAI) reporting over the past two years.

- Pennsylvania hospitals have been expected to report HAIs in a field on the Uniform Bill. PHC4 has compared what hospitals have reported as HAIs using the Centers for Disease Control and Prevention (CDC) definitions against what secondary diagnoses codes on the Uniform Bill that are indicative of an infections. There is a tremendous variation between what hospitals have reported as an HAI and what is included on the Uniform Bill as a secondary diagnoses code. In 2004, the number of secondary diagnosis codes included on all Pennsylvania hospital claims was 115,631 versus a total of 11,668 reported HAIs.
- Many Pennsylvania hospitals have audited all or a sample of their medical records to determine whether those with a secondary diagnosis code indicative of infection should have been reported by the hospital as an HAI. In all of the reviews, hospitals have found that somewhere between 10-18 percent of all cases with a secondary diagnosis code indicative of infection are truly HAIs. Most hospitals that have reviewed medical records with a secondary diagnosis code indicative of infection have discovered that they have only overlooked a few cases that should have been reported to PHC4 as a HAI.
- As a result of the emphasis on infection as a complication, Pennsylvania hospitals have relayed to HAP that medical records coders will use physician documentation in the record for suspected infection to code for an infection even if there is no confirmed infection. In a recent hip and knee report issued by PHC4, hospitals and physicians were asked to sign off on records with codes that were indicative of infection. Upon review of these records, hospitals and physicians noticed that medical records personnel used a secondary diagnosis code that indicated an infection because the patient was receiving antibiotics for a possible or suspected infection at the time of discharge. Following discharge, results of laboratory specimens collected while the patient was hospitalized conclusively determined that there was no infection. According to hospital compliance officers, making any changes to the medical record based upon what you know following discharge versus what you know at the time of discharge raises compliance issues in and of itself since coding should reflect what you know at the time of discharge. This again points out some of the weaknesses in using secondary diagnosis codes to indicate the presence of a true hospital-acquired infection.
- In a recent article, "Administrative Data Fail to Accurately Identify Cases of Healthcare-Associated Infection," published in the April 2006 *Infection Control and Hospital Epidemiology,* Children's Hospital of Philadelphia concluded, "... review of administrative data failed to provide accurate data on 4 of the most common HAIs (central-line associated bloodstream infection, catheter-associated urinary tract infection,

ventilator-associated pneumonia, and surgical site infections). Most of the cases classified as HAIs by review of administrative data were misclassified. Although review of administrative data had a sensitivity of 61 percent (compared to 76 percent for targeted surveillance), its positive predictive value for identifying cases of HAI was 20 percent as compared to 100 percent for targeted surveillance."

- Children's Hospital of Philadelphia also found that the most common reasons for HAI misclassification in billing data was that no laboratory-confirmed infection was present. Many misclassified HAIs occurred in patients with no exposure to devices (central venous catheters, urinary catheters, ventilators) or surgical procedures. And, finally hospital billing data misidentified many outpatient infections as HAIs. This latter issue could be addressed in part but not completely by having hospitals identify patients with known infections as being present on admission.
- In another study performed by a Pennsylvania hospital, the hospital determined that use of secondary diagnoses codes to predict the presence of a urinary tract infection was a poor predictor of the presence of actual urinary tract infections. In this same study, the hospital found that most patients diagnosed by physicians were probably just colonized with bacteria—not infected. Additionally, this investigation found that for most patients diagnosed with a hospital-acquired urinary tract infection, there was little impact on their hospitalization. Although catheter-associated urinary tract infection may account for a substantial volume of HAIs, HAP does not believe that this is a condition that should be considered by CMS because of its limited impact on patient mortality and morbidity. Furthermore, it does not appear that the presence of a urinary tract infection would bump a case into a higher paying DRG.
- With respect to other HAIs that may be candidates for consideration by CMS to implement the provisions included in the DRA, probably the best conditions to consider would be central-line associated bloodstream infections and/or surgical site infections because there are evidence-based guidelines that should be utilized to prevent the occurrence of these infections in hospitals. Additionally, the occurrence of these infections can lead to costly treatment, longer lengths of stay, and increased patient morbidity and mortality. Unfortunately, there are also drawbacks to using these conditions, namely that there is not a distinct secondary diagnosis code for a central-line associated bloodstream infections. Because of the shorter hospital lengths of stay, surgical site infections may not manifest until after the patient is discharged. Treatment of these surgical site infections may be able to be managed as outpatients. Some patients with surgical site infections might require hospital readmission for treatment, but the patient may not necessarily present to the same hospital where the surgical procedure was performed for treatment.
- The other HAI that is receiving considerable attention as a preventable infection is ventilator-associated pneumonia. Ventilator-associated pneumonia carries with it the potential for substantial morbidity and mortality, but these infections are difficult to detect accurately. Even though a CDC definition exists, many in Pennsylvania's infection control community continue to express concern over the high level of subjectivity that exists in making a determination of ventilator-associated pneumonia. And, as is the case with central-line associated bloodstream infections, there is not a specific secondary diagnosis code for ventilator-associated pneumonia.
- Complications are harmful events or negative outcomes that result from the processes of care and treatment rather than a natural progression of the underlying illness. Complications do not necessarily represent medical errors, since they are not always preventable even with optimal care. Even if the use of secondary diagnosis codes was an

accurate way to detect HAIs, not all HAIs are preventable in every patient. For instance, trauma, burn, organ transplant, and cancer patients may be more susceptible to infection simply because of their disease or condition and not necessarily a result of poor care. Furthermore, while there is consensus that using evidence-based guidelines reduces hospital-acquired infections, it is not clear to what level (80 percent, 90 percent, 100 percent) such infections can be reduced through strict adherence to the guidelines. In order to implement this model, CMS will need to do extensive work to subject the reimbursement schema only to those potentially preventable complications.

RECOMMENDATIONS

While there is merit in looking at this concept in order to increase hospital evidence-based guidelines to prevent unnecessary patient complications, HAP remains gravely concerned about actual implementation given the weaknesses in using secondary diagnosis codes as an indicator of a true hospital-acquired complication. As a result of the extensive work that Pennsylvania hospitals have done in the area of HAI reporting, HAP can say that secondary diagnoses codes indicative of infection serve as poor proxies in identifying actual HAIs. Given the proposal outlined by CMS, HAP believes that many hospitals would be penalized in using secondary diagnosis codes as they were developed for use in hospital billing. As already stated, in order to implement these provisions in the DRA, CMS will need to do extensive work to subject the reimbursement schema only to those potentially preventable complications.

Without further investigation, HAP is not certain whether there may be other conditions, such as the development of deep vein thromboses or pressure ulcers that may be more clear-cut and more easily identifiable using secondary diagnosis codes than HAIs and in helping CMS meet the provisions in the DRA of 2005.

MedPAC has also suggested that CMS identify a subset of events that should never happen (for example, wrong site surgery) and either deny payment or pay less for care associated with the event. HAP recommends that CMS explore whether reductions in hospital payments for defined "never events" might be more easily and quickly accomplished and whether implementing reduced payment for cases in which a "never event" occurred would satisfy the requirements in the DRA of 2005. Since there is a uniform standard protocol that should be used by hospitals to prevent wrong-site surgery, reduced payment for performing wrong-site surgery may meet the intent of the DRA provisions.

Finally, as in the previous recommendations related to bonus incentives, this provision will require the involvement of many stakeholders and many opportunities for extensive public comment. HAP recommends that CMS consider a smaller-scale demonstration projects to test any methodology with hospitals before a national implementation.

174

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June 9, 2006

BY HAND DELIVERY

Mark B. McClellan, Administrator
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Re: CMS-1488-P (Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates)

Dear Administrator McClellan:

Ingenix, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule related to the fiscal year 2007 inpatient hospital prospective payment system (" Proposed Rule").[1] As a company dedicated to transforming and improving the efficiency and quality of health care, including government health care, through information and technology, we have been involved with the inpatient hospital prospective payment system ("IPPS") since the advent of the diagnosis related groups ("DRGs"). We provide commercially available software related to IPPS and the DRGs that helps hospitals and health plans ensure proper coding and billing for their inpatient services and that assists these entities in determining the DRG payment rate to facilitate their provision of care in an economic fashion. More Medicare Advantage plans rely on our software for out-of-network pricing than all other sources, combined. In addition, we have developed an alternative classification methodology that, consistent with CMS objectives stated in the Proposed Rule, refines and enhances the current DRG system based on severity of illness. We continuously monitor and analyze CMS DRG changes to ensure that our severity refinement system, as well as all our other coding and reimbursement software, remain compliant with CMS' DRG model.

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[1] 71 Fed. Reg. 23996 (Apr. 25, 2006).

Given the nature of our involvement with IPPS and the DRGs over the years, we have reviewed CMS' proposed changes to the DRG methodology with great interest. These comments focus solely on the proposed refinement of the DRGs based on severity of illness. [2/] On this issue, we offer the following key points that will be discussed in more detail below:

1. Ingenix fully supports CMS' interest in improving and refining the current DRG system. Indeed, we have been working on a methodology to do just that for more than a decade.
2. It is critical that any refinements made to the DRG methodology be accomplished in a manner that is transparent to all affected individuals and entities, and based on public comment and debate, regardless of the basis upon which refinements are made. As explained in more detail below, we view the necessary transparency to involve making any revised methodology fully available in a timely manner and deployed, as is currently the case, in a way that gives no competitive advantage to any firm or organization.
3. Refinements to the DRGs should incrementally build from the current system to preserve the value of existing data, DRG-based quality and consumer initiatives, benchmarks, actuarial "best practice" models and related quantitative information, and to facilitate a smoother transition by hospitals and health plans.
4. Revising the DRG methodology effective October 1, 2006 is not feasible, as none of the interested parties would be ready for a change of this magnitude.
5. Regardless of the basis CMS uses for making refinements to the DRGs, the agency must engage in a full discussion of possible alternative bases for revising the DRGs before implementing any such refinements.

DISCUSSION

I. CMS MUST ENSURE THAT THE CURRENT LEVEL OF TRANSPARENCY IN THE DRG SYSTEM IS MAINTAINED REGARDLESS OF THE CHOSEN METHODOLOGY

As noted earlier, Ingenix (and other companies) offers software that hospitals and health plans utilize in managing the billing, coding, and payment for inpatient hospital services under the DRGs. The development of this software by Ingenix and others is possible only because the current DRG methodology is a transparent system. By that, we mean that members of the public can obtain full access to the details underlying the system by purchasing information and software from the National Technical Information Service at a nominal charge in a timely manner (well in advance of the implementation of

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[2/] As such, all of the comments contained herein are pertinent to the caption "DRGs: Severity of Illness" which the agency asks that commenters identify early in the comment letter.

changes). Every entity can purchase the same products at the same time such that no company can obtain a competitive advantage in producing this software. In addition, CMS currently engages in an open and comprehensive discussion about the structure of the DRG methodology through a variety of mechanisms including notices published in the *Federal Register*. It also releases sufficient detail about its methodology in electronic formats to enable providers, health plans, and vendors to develop and validate their own computer programs based on regulatory standards for DRG assignment.

Ingenix is extremely concerned that this type of unfettered access to the underpinnings of the DRG system will not continue to be available under the refinements identified in the Proposed Rule. Specifically, the Proposed Rule indicates that CMS would use the All Patient Refined ("APR") DRG system as the underlying basis for using the proposed consolidated-severity adjusted DRGs ("CSA DRGs") to refine the DRGs. 71 Fed. Reg. at 24027. As noted in the Proposed Rule, the APR DRGs refers to a severity DRG system designed by 3M Health Information Systems ("3M") that is currently in use in the State of Maryland. 71 Fed. Reg. at 24011. While the proprietary elements of the APR-DRG logic may have been disclosed to CMS in the course of the agency's development of the Proposed Rule, the elements that are necessary to preserve the level of access to the DRG methodology the public currently enjoys have not been shared. This level of sharing is critical to (i) a full public evaluation of any revised methodology; and (ii) the ability of vendors to continue to provide the important information and software products used by hospitals in coding and billing for inpatient hospital services and used by Medicare Advantage plans to pay for Medicare covered services.

In order for the revised system to have the requisite level of transparency to achieve these important goals, all of the following must be made available:

- Software distribution comparable to what is currently made available, which includes:
    - Grouper source code which produces all pertinent return information;
    - All underlying tables that drive the Grouper with documentation;
    - A complete set of test cases to validate the functioning of the software;
    - Complete system and user documentation;
- Contact people who can and will respond to questions in a timely fashion;
- The right to re-distribute the methodology to business partners and consultants;
- The right to translate source code to other technology environments and to integrate it into other systems;
- Pre-releases of software and documentation well in advance of planned implementations; and
- An open and inclusive process for considering future enhancements.

However CMS moves forward with refining the DRGs, the agency must ensure that all aspects of the methodology are transparent and fully available to the public, as is true now. The agency must also ensure that whatever refinement methodology is adopted is

open to public discussion and scrutiny, now and on an ongoing basis. Transparency is critical to advancing affordability in our health care system.

II. The Public Is Denied a Meaningful Opportunity to Comment on the Proposed Rule Because Incomplete Information is Available Concerning the APR-DRGs

Under the Administrative Procedure Act ("APA"), an agency has an obligation to include sufficient information on the proposed rule so that the public can evaluate the proposal in a meaningful fashion. 5 U.S.C. § 553.[3] As the Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") has explained, "[t]o allow an agency to play hunt the peanut with technical information, hiding or disguising the information that it employs, is to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." Connecticut Light & Power v. NRC, 673 F.2d 525, 530-31 (D.C. Cir. 1982), *cert. denied* 459 U.S. 835 (1982). Moreover, where agency action is based on technical data and calculations, the agency is obligated to release that information to allow for public analysis and comment.[4] Certainly, refinements to the DRGs would be based on technical data and calculations such that CMS has a heightened obligation to release sufficient information to allow the public to comment on its proposal.

While CMS seeks comment on the use of APR-DRGs in refining the current system, neither the agency, nor its contractor has made available sufficient details about the proposed methodology for the public to comment meaningfully. For example, the public cannot access the Grouper source code, the underlying table driving the Grouper, and complete system and user documentation. This information is not available through the CMS website or the 3M website referenced in the Proposed Rule. Because of the lack of information available through these sources, Ingenix requested the necessary information from 3M directly. In a response dated May 1, 2006 (copy attached), 3M refused to provide further information, referring Ingenix to the website CMS mentioned in the Proposed Rule that does not contain the necessary detail.

As a result, the public does not have access to the "batch" software to assign cases to either the proposed "consolidated severity adjusted" DRGs (CSA-DRGs) or the 3M APR-DRGs, the underlying base for the CSA-DRGs. The only automated tool available is one offered on the 3M website which allows for the grouping of a single case into an APR-DRG and what appears to be the CSA-DRG, but is labeled "consolidated APR

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[3] *See* United States v. Novia Scotia Food Prods. Corp., 568 F.2d 240, 252 (2d Cir. 1977) ("To suppress meaningful comment by failure to disclose the basic data relied upon is akin to rejecting comment altogether").

[4] E.g., Engine Mfrs Ass'n v. EPA, 20 F.3d 1177, 1181 (D.C. Cir. 1994) (when technical or scientific data are the basis for the proposed rule, the promulgating agency must release data underlying the rule so that interested parties may comment).

DRG". Without software capable of processing large batches of data, it is not possible for providers or supporting organizations to fully understand, model and evaluate the impact of the proposed changes on hospital payments (e.g., how specific coding practices impact the APR-DRG classification process and expected reimbursement).

As CMS acknowledged in a recent Open Door Forum, it is not possible to crosswalk the current DRGs to the APR-DRGs or the proposed CSA-DRGs. Without a crosswalk, it is difficult to understand and evaluate the impact of the proposed Grouper change. The only substitute for lack of a crosswalk is the ability to process large volumes of data through the new CSA-DRG assignment algorithm, so that current DRG assignments can be compared with new CSA-DRG assignments, and patterns of change can be identified at a more global level. Patterns can not be identified by processing individual records using the tools made available by CMS. Most members of the public would not have the ability to process such large volumes of data, thus depriving most prospective commenters of the opportunity to provide meaningful comments to CMS on the assignment of cases to CSA DRGs.

In addition, without access to CSA-DRG Grouper source code, tables and documentation, it is not possible for hospitals, health plans or vendors to fully evaluate the technical aspects of adopting the proposed severity adjustment methodology. We do not know how the CSA-DRGs will be packaged and distributed. Without a sample Grouper software distribution to work with, it is not possible to evaluate the level of difficulty in implementing or supporting this newly proposed Grouper or the ability to translate the grouper algorithm to different technology environments.

In our view, the failure to provide access to details about the proposed methodology and its technical implementation, limits the types of information that CMS could obtain through the public comment process if sufficient details about the methodology were made available. Such comments would be very valuable to CMS in determining how to refine the DRGs and how to implement a refined methodology, while limiting the administrative costs of implementing and transitioning to this methodology. We, therefore, urge CMS to make this type of information available to the public and allow the public sufficient time to analyze this information and offer comments to the agency before any refinements are made to the DRGs (regardless of what methodology underlies the refinements). Indeed, in order to act in a manner consistent with the APA, the agency must not adopt DRG refinements based an APR-DRG methodology beginning in fiscal year 2007 because of the lack of a meaningful opportunity to comment on this issue.

III. CMS Has Failed to Consider Alternate Bases for Revisions to the DRGs

The notice requirements for rulemaking under the APA also require agencies to include consideration of alternatives to the proposed action during the rulemaking process. As noted by the D. C. Circuit, an agency must take affirmative steps to "demonstrate that it afforded adequate consideration to every reasonable alternative presented for its consideration." Professional Pilots Federation v. FAA, 118 F.3d 758,

763 (D.C. Cir. 1997). Indeed, the failure to respond to significant alternatives presented by the interested public can present problems for a final rule upon judicial review. [5] Similarly, the Supreme Court has said that an agency rule can be found to be arbitrary and capricious due to the failure to consider an important aspect of the problem. [6]

The Proposed Rule reflects no consideration of alternatives to the APR-DRGs for refining the DRGs. Rather, the agency states that "it is possible that the public comment process will present compelling evidence that there are potential alternatives to the consolidated severity-adjusted DRG system for us to consider that could more effectively recognize severity of illness." 71 Fed. Reg. at 24011. In moving toward such a monumental change to IPPS, the agency's obligation is to do more than focus on a single basis for change and offer the possibility of considering alternatives in the short window between the close of the public comment period and the issuance of the final rule. CMS has the obligation to not only consider alternatives, but also to objectively evaluate the alternatives that it considered. Neither occurred here.

The failure to consider alternative bases to the APR-DRGs is surprising given that a number of alternatives exist that are known to CMS and other HHS agencies. In fact, the Agency for Health Care Research and Quality ("AHRQ") conducted a thorough evaluation of alternative severity adjusted systems for use in its Healthcare Cost and Utilization Project ("HCUP") – a set of databases and software tools developed to build a health data system for health care research and decisionmaking. As a result of this evaluation, AHRQ selected the All-Payer Severity-adjusted DRGs® ("APS-DRGs®"), which Ingenix has developed, as one of three severity-adjustment systems to be used as part of this project. [7] In addition, CMS itself developed an alternative DRG methodology in the early 1990s known as the Severity-adjusted DRGs ("SDRGs"). [8] Further, researchers at Yale University developed Refined DRGs ("RDRGs") in the late 1980s under a Cooperative Agreement with the Health Care Financing Administration (now CMS). It is possible that there are other additional alternative bases upon which to refine the DRGs, but there are at least three practical alternatives to the APR-DRGs with which we are familiar.

None of these alternatives is mentioned in the Proposed Rule. This is especially surprising given that, in the Department of Health and Human Services interim report to Congress regarding specialty hospitals submitted on May 9, 2006, there is mention of the

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[5] *See* City of Brookings Municipal Telephone Company v. FCC, 822 F.2d 1153, 1169 (D.C. Cir. 1987) (*quoting* Yakima Valley Cablevision v. FCC, 794 F.2d 737, 746 n. 36 (D.C. Cir. 1985) ("failure of an agency to consider obvious alternatives has led uniformly to reversal")

[6] *See* Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insur. Co., 463 U.S. 29, 43 (1983).

[7] *See* http://www.ahrq.gov/data/hcup/datahcup.htm.

[8] Edwards, N., Honemann, D., Burley, D., Navarro, M., "Refinement of the Medicare Diagnosis-Related Groups to Incorporate a Measure of Severity," Health Care Financing Review, 16(2) (1994): 50-51.

potential changes to the DRG system and a statement that CMS "intends to fully analyze all these changes and is eager for a full and comprehensive discussion with the hospital community."[9] The agency can only fulfill this intention by considering alternatives to the APR-DRGs, and that cannot be done by revising the DRG system effective October 1, 2006. Instead, the agency must identify other alternatives, provide its views on such alternatives, and consider the views of the hospital community on the alternatives.

IV. The Proposed Rule Fails to Adequately Examine the Impact of Making DRG Refinements Based on the APR-DRGs

CMS has acknowledged that refining the DRGs will be a significant undertaking that likely will have a substantial effect on all hospitals. 71 Fed. Reg. at 24011. Yet, the Proposed Rule fails to examine in a serious manner the impact of using the APR-DRGs in refining the DRGs because, among other things, it understates the complexity of the APR-DRGs and does not discuss the impact of moving to APR-DRGs where that has occurred.

A. The APR-DRGs Represent a Significant Conceptual Shift

The Proposed Rule understates the complexity of the APR-DRG methodology, leading readers to believe that APR-DRGs are an improvement upon the CMS model rather than a replacement of the CMS model. APR-DRGs would be a significant conceptual shift and hospitals would have more difficulty adapting to it than is suggested by the Proposed Rule. Some key differences in adopting the APR-DRGs, as compared to the CMS DRGs, are highlighted below. Note that this analysis is based on our understanding of the APR-DRGs, as documented on the 3M website and in the publicly available documentation of the methodology.

- APR-DRGs were built upon 3M's proprietary All Patient DRG ("AP-DRG") model[10]; they are not built upon the current CMS DRG model. This means that the base DRGs which underlie the APR-DRGs are not the same as the base DRGs that underlie the CMS DRG Grouper. "The AP-DRGs introduce many other changes to the CMS DRGs. Some of these primarily affect pediatric patients while others affect patients of all ages."[11] Moving to APR-DRGs means adopting the underlying AP-DRG base groups, as well as adopting severity adjustment. Many hospitals have no experience with the AP-DRG Grouper.
- Traditionally, the first step in DRG assignment is to assign a case to a Major Diagnostic Category ("MDC") based on the patient's principal

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[9] *See* http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/051006adminreport.pdf, at p.2.

[10] Pages 3 and 25 of 3M APR DRG v23 Definitions Manual, Volume 1 as posted to www.aprdrgassign.com.

[11] Page 17, 3M APR DRG v23 Definitions Manual, Volume 1 as posted to www.aprdrgassign.com.

diagnosis. The one exception to this within the CMS DRGs is called pre-MDC processing, as discussed in the following point. Within the APR-DRGs, however, there is complicated logic that ignores the principal diagnosis and re-routes cases to a different MDC. Re-routing across MDCs occurs when "the principal diagnosis is overly broad, or the sequencing of principal diagnosis and secondary diagnosis is unclear, or a surgical procedure provides clarification of the principal diagnosis."[12] Because this "re-routing" logic is complicated and has no parallel in the CMS DRGs, it will take hospitals some time to learn and fully evaluate this logic.

- Both the CMS DRGs and the APR-DRGs have processing that occurs prior to assignment to an MDC based on principal diagnosis. This "pre-MDC" logic addresses situations where "there is a clear patient characteristic that should take priority, such as for a patient with an organ transplant or a tracheostomy in the absence of an ENT problem."[13] Pre-MDC hierarchies and categories are substantially different between the APR-DRG model and the current CMS DRGs. For example, the eligibility requirements and definitions of the MDCs for "multiple significant trauma" and HIV are different, as well as the definition of the DRGs for tracheostomy patients. In fact, the numbering of the MDCs for Multiple Significant Trauma and HIV (CMS MDCs 24 and 25) are reversed within the APR-DRGs, where MDC 24 is for HIV patients and MDC 25 is for "multiple significant trauma". While this is confusing, it is more important that the logic for assigning cases to these MDCs is significantly different, as well as the composition of the DRGs within each MDC. For example, in the APR-DRGs, certain diagnoses only represent significant trauma if specific operating room procedures are present.[14]
- The list of procedures considered to be operating room procedures for purposes of DRG assignment is different in the APR-DRGs versus the CMS DRGs.
- The assignment of principal diagnosis codes to specific MDCs is different in the APR-DRGs as compared to the CMS DRGs. We have noted changes in at least four MDCs: 3, 17, 21 and 23.
- Surgical hierarchies are different for many MDCs.
- Some MDCs use completely new criteria for DRG assignment. MDC 20, for example, differentiates patients based on the substance abused.
- In addition to all of the above, which are only a sampling of the methodological changes between the APR-DRGs and the CMS DRGs, hospitals will need to learn new rules for assignment of severity levels.

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[12] Pages 29 and 30 3M APR DRG v23 Definitions Manual, Volume 1 as posted to www.aprdrgassign.com.

[13] Pages 29 3M APR DRG v23 Definitions Manual, Volume 1 as posted to www.aprdrgassign.com.

[14] Page 28, 3M APR DRG v23 Definitions Manual, Volume 1 as posted to www.aprdrgassign.com.

All hospitals and most payers are familiar with the CMS DRGs. They understand the basic constructs of these Groupers. Hospitals have planned their inpatient coding, compliance and billing processes around the CMS DRG for years. Payers have built reimbursement and editing rules around the same DRG constructs. CMS DRGs are fundamental to the hospital's management and planning processes. Today's healthcare industry is data driven. It relies upon complete and correct data for making decisions and for reimbursement. Accurate coding and billing is fundamental to this process. As the fundamentals of DRG assignment change, so must all the associated processes, edits and clinical logic which is DRG-based and assures good quality data. Hospitals, vendors and payers will all need to re-evaluate how the AP-DRG/APR-DRG model differs from the CMS model and update their processes accordingly.

B. The Proposed Rule Failed to Discuss Concerns with the Methodology Where it is in Use

As CMS noted in the Proposed Rule, APR-DRGs have been in use in Maryland since July of 2005. 71 Fed. Reg. at 24011. Remarkably, the agency offers no critique of this methodology in practice. Before refining the DRGs based on the APR-DRGs, CMS needs to discuss the impact of this methodology on hospitals in Maryland, including various concerns that the implementation of the APR-DRGs has engendered.

On the provider and payer side, there have been significant operational burdens of the move to the APR-DRGs in Maryland. In general, Maryland hospitals have experienced a reduction of 20 to 30 percent in the productivity of their coding staffs because APR-DRGs create incentives for coders to assign diagnoses and procedures as comprehensively as possible, in light of the decision logic in the APR-DRG algorithm. Such changes in productivity have forced hospitals to either (1) hire and train additional coding resources to manage the existing caseload or (2) allow the coding backlog and receivables to increase. Hospitals that relied on a vendor other than 3M for their encoding and casemix classification systems found that vendors were challenged to meet their needs in a timely manner and experienced significant increases in software license fees. In some cases, they were compelled to abandon their preferred products in favor of 3M software to maximize their reimbursement. Finally, it is worth noting that Maryland required 3M to conduct a number of educational sessions around the State prior to implementation of APR-DRGs because of the differences between the APR-DRGs and the previous casemix classification system, which was based on the Medicare DRGs. These educational sessions were designed to help hospitals understand the fundamental differences between the two systems, so that they could understand changes in coding practices that would be required under APR-DRGs.

The anecdotal information about casemix changes in Maryland suggests that these educational sessions were quite successful. We understand, from the Health Services Cost Review Commission, that measured casemix rose more than four percent in Maryland during calendar year 2005. There is virtually no evidence that this increase reflects a real casemix change. It is almost entirely due to changes in coding practices

induced by the adoption of APR-DRGs. Because APR-DRGs provide a mechanism for hospitals to increase revenue by more complete coding than they currently engage in, similar aggregate increases can be expected nationally if CMS decides to adopt this classification system. Since a one percent increase in measured casemix translates almost directly into a one percent increase in hospital payments under the Medicare IPPS, CMS will either need to prepare for rapid increases in inpatient hospital reimbursement or it will need to develop a strategy for distinguishing between real changes in casemix and artificial changes created by more comprehensive coding.

Further, information technology ("IT") vendors that assist hospitals in billing, coding, and reimbursement in Maryland have had difficulties continuing to serve their clients' needs because of the actions taken by 3M that seem calculated to facilitate increasing 3M's client base in Maryland for this business. Specifically, vendors have experienced delays in entering into agreements with 3M regarding the APR-DRGs and have experienced delays/denials in licensing key components of the system. In addition, 3M has refused to provide test cases that would allow vendors to test the software created for hospital clients. Also, vendors have encountered unresponsiveness in contracting, support, and product implementation by 3M. Each of these actions makes it more difficult for other vendors to assist their clients, difficulties that 3M has not had to confront. That provides 3M with a competitive advantage in this market, and Ingenix is very concerned that similar actions would be taken if APR-DRGs were used for refining the DRGs. In the final rule, CMS must make clear that it will not allow any entity whose methodology may be used in refining the DRGs to obtain a competitive advantage as a result.

C. Other Impacts that CMS Must Address

In examining the impact of a refinement of the DRGs, there are a number of other items that CMS should consider. For example, CMS must address how a move to the use of APR-DRGs would affect other payment mechanisms, including other Medicare prospective payment systems, Medicaid programs, and other government health care programs that utilize the DRGs. The agency has recently released rules on the prospective payment systems for psychiatric hospitals and long-term care hospitals which either did not mention APR-DRGs or made clear that there would be no immediate impact as a result. Yet, the agency did not explain how these systems could continue to use the DRGs if, on October 1, 2006, the DRGs had been refined. Similarly, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), which provides health services supplemental to that available in military and Public Health Service facilities, uses the "same DRGs used in the most recently available grouper for the Medicare Prospective Payment System" to determine payment rates for many inpatient hospital services. 32 C.F.R. § 199.14(a)(1)(i)(A). CMS does not explain how CHAMPUS would be impacted by a change in the DRG methodology.

In addition, there appears to be no consideration of the interplay of refining the DRGs and moving to the International Classification of Diseases, Tenth Revision ("ICD-10). A move to ICD-10 also would be a substantial change and we are concerned on the

impact on hospitals of dealing with refinement to the DRGs in one year and moving to ICD-10 a year or two later. CMS should consider the merits of refining the DRGs in a manner that builds on past practice to minimize the burden placed on the industry in light of the impending implementation of ICD-10. Moreover, CMS must carefully examine whether the methodology chosen to revise the DRG will lock the agency into an uncompetitive procurement process, a concern discussed in Section V below. CMS must provide an objective evaluation of costs and benefits to industry, which appears to be absent from the Proposed Rule. Finally, CMS must detail how the use of APR-DRGs will affect health care costs.

V. The CMS Proposal to Utilize APR-DRGs is the Result of Improper Contracting Relationships

Ingenix is concerned about the agency's contracting relationships regarding IPPS. For many years, CMS has contracted with 3M to operationalize its policy decisions regarding IPPS. In last year's final rule, the agency announced that it was in the process of engaging a contractor to review recommendations made regarding DRG refinement. 70 Fed. Reg. 47278, 47479 (Aug. 12, 2005). That contract was awarded to 3M without the solicitation of competitive bids. Despite the fact that there are a number of companies well-equipped to perform these tasks, CMS determined that it was appropriate to award a sole source contract to 3M for this work. The agency's determination is problematic on a number of levels.

The CMS contract with 3M does not meet the Federal Acquisition Regulation standards to be considered a "sole source" contract. There were other entities capable of performing the work. It would be inappropriate for CMS to suggest, in these circumstances, that time was an appropriate basis for designating this as a sole source contract. Further, the agency failed to describe its efforts to ensure that offers were solicited and that market research was conducted, as required by regulation. *See* 48 C.F.R. §§ 6.303-2(a)(6), 6.303-2(a)(8) (justification to support a sole source contract must include a description of efforts to ensure that offers were solicited and a description of the market research conducted).

Ingenix is also concerned about the conflict of interest in awarding the contract to 3M. According to the Proposed Rule, one task of the contract called on 3M to analyze "the feasibility of using a revised DRG system under the IPPS that is modeled on the APR DRGs Version 23 to better recognize severity of illness." 71 Fed. Reg. at 24011. In essence, this called for 3M to provide an evaluation of its own proprietary software as the basis for a revised DRG system. This is inherently a conflict of interest, as that entity would surely want its proprietary software to be sold to CMS for use in IPPS. Thus, it is not clear how CMS could expect 3M to objectively evaluate its own software and the alternative systems. Moreover, there are additional benefits for being the entity whose system is being used for IPPS, as is evident from the attached release from 3M prematurely trumpeting Medicare's adoption of its APR-DRG methodology for its own marketing purposes.

However CMS moves forward with the methodology for IPPS, the agency should keep itself in a position to use a competitive procurement process to obtain needed assistance with the methodology.

VI. None of the Pertinent Parties Will be Ready to Implement a Methodology Change to the DRGs on October 1, 2006

According to the Proposed Rule, there was insufficient time between the release of the March 2005 MedPAC report and the publication of the fiscal year 2006 final rule in August 2005 for CMS to analyze fully the magnitude of a change to APR-DRGs. 71 Fed. Reg. at 24011. Yet, now, in suggesting that it may change the DRG methodology for FY 2007, the agency seems to believe that the public can do a full review of the APR-DRG methodology in less than two months, significantly less time than CMS found inadequate for performing such a review. In addition, it appears that CMS believes that it can now receive comments from the public on APR-DRGs and other refinement alternatives and conduct a full analysis of these APR-DRG comments and alternative methodologies in three months less than existed last year. Clearly, this is not a reasonable approach to "a change of this magnitude." Id. Ingenix respectfully submits that none of the key parties to the DRG refinements based on the APR-DRGs – CMS, the hospitals, and IT vendors – will be ready for an October 1, 2006 implementation.

A. CMS

CMS will not have taken the necessary actions for an October 1, 2006 implementation of DRG refinements based on the APR-DRGs. The agency will not have not satisfied the following crucial procedural obligations preceding such a change:

- Consider and evaluate alternative methodologies to utilize;
- Provide sufficient information on APR-DRGs so that the public has a meaningful opportunity to comment;
- Examine the impact of a move to APR-DRGs;
- Consider the interplay of ICD-10; and
- Engage in proper procurement processes, including avoiding conflict of interests.

In the Proposed Rule, CMS identifies one of its concerns about the APR-DRGs as the failure to contain a method for recognizing technologies that represent increased complexity, but not necessarily a greater severity of illness. The Proposed Rule does not indicate how the agency would address this specifically, but rather that it plans to develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system. 71 Fed. Reg. at 24014. Obviously, CMS will not be ready to implement this important aspect of the methodology on October 1, 2006 and should not move forward on a revised DRG system until all of the important adjustments are in place.

B. Hospitals

Based on our extensive experience with hospitals as clients on IPPS issues, Ingenix suspects that hospitals will not be prepared for a change of this magnitude in four months. They would have to train their coding and billing personnel on the significant changes and, for reasons discussed earlier, there is insufficient information available in the Proposed Rule to begin that training. It seems infeasible to believe that training on changes this substantial that would not begin until after the IPPS final rule is issued could be accomplished by October 1, 2006.[15] Indeed, the trainers would need time after the final rule is issued to understand the new system so that they could, in turn, train others. Moreover, hospitals would have to alter their computer systems as a result of the DRG refinements. Again, it is not clear that this would be feasible after the final rule and prior to October 1.

C. IT Vendors

IT Vendors will not be able to continue to service their hospital or Medicare Advantage customers on October 1, 2006 under a revised DRG system discussed in the Proposed Rule. As discussed earlier, vendors need access to the details of the methodology so they can build hospital-specific software and training programs. There is insufficient information available now to do that and, even when the final rule is released, the underlying details of the methodology would have to be released for these programs to be built.

It is clearly not realistic to expect any vendor to develop casemix classification software based on the current tools that have been made available to the public: (1) a Definitions Manual that consists of 2 volumes and nearly 3,000 pages and (2) a simple, internet-based tool that allows users to enter one case at a time and obtain the corresponding APR-DRG assignment. The Definitions Manual, although available for review during the comment period, is copyrighted to 3M and its uses are restricted. Indeed, information that has been released to support the Proposed Rule seems calculated to satisfy minimal disclosure standards and, at the same time, to demonstrate to the entire industry that will need to depend upon a single, monopolistic source of information and support for the new Medicare casemix classification system. To avoid an unseemly display of regulatory-induced market power, it is essential that CMS ensure that vendors have the type of support identified earlier in our discussion of transparency including source code, relevant code lists in electronic formats, and a comprehensive set of test cases. And these CMS assurances need to be clearly stated in the Final Rule.

VII. Conclusion

Again, Ingenix appreciates the opportunity to comment on the important issues raised by the Proposed Rule. As detailed above, we have a number of serious concerns

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[15] The only way hospitals would be ready for such a change effective October 1, 2006, would be if the agency used a methodology that builds from the current DRGs, which the APR-DRGs do not.

about the proposals related to the refinement of the DRGs. To address these concerns, Ingenix respectfully urges CMS to

1. Ensure that a transparent methodology is used as the basis for refining the DRG, meaning that the same level of information (e.g., open source code, full documentation, test files, open process for updates, timely dissemination of information) is available as is currently true.
2. Implement refinements no sooner than October 1, 2007 and after the public has had a meaningful opportunity to comment.
3. Carefully consider the burdens of implementing refined DRGs based on the APR-DRGs, with particular consideration on the use of APR-DRGs in Maryland.

If you have questions concerning this letter, please do not hesitate to contact Bob Leary at (860) 221-0582. Thank you for your consideration.

Sincerely,

Richard Anderson
Chief Executive Officer

Enclosures

Attachment 174

3M Health Information
Systems Division

575 West Murray Boulevard
Murray UT 84123-4611

3M May 1, 2006

Robert Leary
CEO
HSS, An Ingenix Company
2321 Whitney Avenue
Hamden, Connecticut 06518

Dear Mr. Leary,

I am in receipt of your letter dated April 24, 2006 concerning the relationship between our two organizations in light of the policy initiatives underway in the State of Maryland and by the Center for Medicare and Medicaid Services (CMS).

With respect to activities in the State of Maryland, it is my understanding that Lee St. Clair, from my organization, communicated to Kevin Lucey on April 11, 2006 that 3M has decided to broaden the scope of our APR DRG-SOI product available to our vendor partners to include the following data elements:

- APR DRG classification
- MDC
- SOI patient level
- SOI secondary affect flags
  - includes yes/no flags to identify that diagnosis impacts both the APR DRG
  - includes yes/no flags to identify that diagnosis impacts the SOI level of the patient
  - Secondary diagnosis level of impact
- Re-sequencing of secondary diagnoses
- Weight (3M provided national charge based weight unrelated to any payment weight developed by CMS)
- Trim points (3M provided LOS trim points unrelated to any outlier methodology developed by CMS)
- LOS inlier/outliers (Outlier status based on 3M LOS trim points unrelated to any outlier methodology developed by CMS)

In addition, 3M has offered to broaden the scope of the license to permit HSS to have nationwide distribution rights to our APR DRG-SOI product commensurate with those we are willing to make available to similarly-situated vendors.

With respect to activities being undertaken by CMS, CMS is, as you know, currently in the public comment period of its proposed rule-making process. As a result, and in all fairness to similarly-situated vendors, we do not believe that it would be appropriate for 3M to engage in one-off discussions or negotiations with HSS, or any other vendor, at this time. To the extent that you have APR DRG-related questions, we would refer you to the following excerpt from the *Federal Register*:

> "In order to facilitate understanding of the underlying severity DRG concepts and logic, we are providing a link below to 3M's Web site for the duration of the comment period where users can access information related to the proposed consolidated severity-adjusted DRGs. Users will have access to a tool that allows them to build case examples using this proposed DRG classification system. The report produced by the tool will provide a detailed explanation of how the severity of illness was assigned and the diagnostic and demographic factors affecting that assignment. In addition, users will be able to view the APR DRG Definitions Manual, a report showing the mapping from the standard APR DRGs to the consolidated severity-adjusted DRGs, a report showing basic APR DRG statistics, and other APR DRG background and educational materials. This site can be accessed at: http://www.aprdrgassign.com."

We encourage you to visit this website, and to avail yourself of the opportunity to send your comments on this issue directly to CMS as specified in the *Federal Register*.

Very truly yours,

Nancy A. Larson

Nancy A. Larson
Vice President
Health Information Systems Division

3M Health Information Systems

CMS Proposes Changes to Inpatient Prospective Payment System

Are You Prepared for Medicare Inpatient PPS Changes?
On April 12, 2006 a copy of the *Federal Register* that will be published April 25 was put on public display. In this Notice of Proposed Rulemaking CMS proposes sweeping changes to the DRG-based inpatient prospective payment system (IPPS). The proposal includes a new method for establishing DRG-payment weights and replacing the current DRGs with a consolidated version of the All Patient Refined DRGs (APR DRGs). CMS is proposing to implement the new method for establishing DRG-payment weights on Oct. 1, 2006 and implementing the consolidated version of 3M APR DRGs on Oct. 1, 2007. CMS is soliciting comments on the timing and scope of these changes during the 60-day comment period that follows publication. During this In addition to the IPPS reforms, the recently enacted Deficit Reduction Act (DEFRA) requires hospitals beginning Oct. 1, 2007, to report on Medicare claims whether a diagnosis was present on admission.

What is the 3M APR DRG Classification System?
3M APR DRGs were developed by 3M Health Information Systems to refine the basic DRG structure by adding four severity-of-illness subclasses. Since the release in 1990, 3M APR DRGs have become a widely adopted for measuring hospital performance and outcomes by health services researchers, including the Agency for Health Care Research and Quality (AHRQ).

What are Your Challenges?
• 3M APR DRGs demand a level of complete and accurate documentation and coding well beyond what is needed with current DRGs. Failure to document and code to this level may result in a hospital not getting the full payment to which it is entitled.

• The new present-on-admission (POA) data required by the DEFRA will directly impact Medicare payments and will likely be used by other payers in pay-for-performance systems. Accurately coding the POA status of every diagnosis with minimal impact on coder productivity will require significant training and planning.

How Might you Prepare for Potential IPPS Reforms
3M solutions provides the tools and expertise to help you make a successful transition to 3M APR DRGs.

- **Comprehensive Impact Analysis and Education**
  Industry-leading experts on 3M APR DRGs provide a full menu of services, ranging from introductory seminars to clinical staff documentation improvement services.
- **Accurate Coding and Documentation**
  3M's sophisticated, expert logic-driven encoder is used by more than 5,500 hospitals worldwide to inform coders of the critical coding issues that impact 3M APR DRG assignment.
- **Customized Performance Measurement**
  3M solutions help calculate the impact of prospective changes to your reimbursement and compare performance to severity-adjusted norms to improve quality.

Rely on the Leader
With decades of leadership and experience with IPPS reform issues and DEFRA, 3M Health Information Systems is uniquely qualified to assist hospitals in successfully managing these far-reaching changes.

For more information on 3M APR DRGs and 3M solutions, contact your local 3M sales representative or visit us at www.3Maprdrg.com.

175

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June 12, 2006

Mr. Marc Hartstein
Deputy Director, Division of Acute Care
Centers for Medicare & Medicaid Services (CMS)
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates (File Code CMS-1488-P)

ISSUE HEADERS: HSRV Weights, DRGs: Severity of Illness, DRG Reclassifications, Proposed Classifications of ICD-9-CM Procedure Codes, New Technology

Dear Mr. Hartstein:

Medtronic is the world's leading medical technology company, providing lifelong solutions to people with chronic conditions. We recognize the critical role acute care hospitals play in providing accessible and high quality care to patients throughout the nation's health care system and we appreciate the opportunity to comment on the FY 2007 proposed hospital inpatient rule.

The Medicare Payment Advisory Commission (MedPAC) recommended and CMS proposed a series of reforms designed to improve the accuracy of payments in the DRG system. We appreciate the significant effort made by CMS staff to develop the most sweeping changes to the calculation of the DRG relative weights and the DRG classification system in the last 20 years.

We fully support the goal of improving payment accuracy in the DRG system. Payments should match costs as closely as possible, and inpatient procedures should be neither overpaid nor underpaid. With these principles in mind, we have a number of serious methodological and policy concerns with the DRG reforms in the proposed rule, and believe significant additional work and analysis is necessary before any major reforms are ready to be put in place.

Medtronic offers the following comments and recommendations on the FY 2007 proposed inpatient rule, and we look forward to working with CMS on revisions to the DRG system that will more confidently improve the accuracy of the inpatient prospective payment system. Of utmost importance, Medtronic recommends that any move to cost-based weights in IPPS must be accompanied by an adjustment to correct for the issue of charge compression for implantable devices.

- **Delay Implementation of New DRG Weight-Setting Methodology to FY 2008 to Make Significant Methodological Improvements and Allow Adequate Stakeholder Analysis and Review**

Given the wide range of issues in the proposed rule on the HSRVcc weights and the consolidated severity adjusted DRGs, we believe it is not possible for the policy or methodological problems to be addressed during the comment period, or for a suitable alternative to be put in place in the final rule with appropriate opportunity for subsequent public review for FY 2007. Moreover, cost-based weights and severity-adjusted DRGs should be instituted at the same time in order to avoid repeated sharp fluctuations in payment to hospitals from year to year – but it appears that neither approach can be ready for FY 2007.

FY 2007 weights should therefore be based on the existing charge-based methodology, which has been in use for the past 21 years. Given the magnitude of the proposed changes, the potential impact on patient access to care, and the importance of getting the weight-setting policies and methodologies right the first time, we believe it is necessary and reasonable to defer the implementation of DRG reforms until FY 2008, when further review and analysis can be dedicated to the issue and broader consensus can be formed.

- **Replace HSRVcc with Traditional Cost-Based Weights and No HSRV**

CMS' proposed HSRVcc approach raises serious methodological and policy concerns. The HSRVcc methodology is a new and unstudied approach that differs significantly with the recommendations modeled by MedPAC on cost-based weights and HSRV. Initial analyses by hospital groups suggest that the impact of the HSRVcc methodology is substantially different than the MedPAC recommendations, and the methodology may even *decrease* payment accuracy relative to current charge-based weights.[1]

The proposed 10 national cost-center format used in HSRVcc exacerbates the known issue of charge compression in setting cost-based weights. In addition, methodological flaws in the trimming of data and the calculation of cost-to-charge ratios give an inaccurate representation of the proposed DRG weights and the distributional impacts of the proposed methodology, and have made it extremely difficult for the rule to be appropriately assessed by the public during the comment period. In Attachments 1 and 2 to this letter, we submit a detailed analysis of the methodological flaws in the proposed HSRVcc DRG weight calculations.

In place of the 10 national cost-center approach, CMS should adopt a traditional cost-based weighting methodology in which the most specific estimates of hospital costs are first calculated and then used to set DRG relative weights. This is comparable to the methodology used to set weights in the hospital outpatient prospective payment system (OPPS). As described below, we believe a move to cost-based weights in IPPS must be accompanied by an adjustment to correct

[1] The Health Economics and Outcomes Research Institute of the Greater New York Hospital Association, "Analysis of the Centers for Medicare & Medicaid Services' Proposals for Changing the Diagnosis-Related Group Weighting Methodology and Patient Classification System in the Inpatient Prospective Payment System," June 12, 2006.

for the issue of charge compression, and by improvements in the use and accuracy of underlying data in hospital cost reports.

The hospital specific relative value (HSRV) methodology should not be adopted with cost-based DRG weights. Past research indicates that HSRV has a disproportionate impact on certain types of hospitals and certain types of care, and reduces the range of DRG weights between the lowest and highest weight DRGs, raising the concern of limiting patient access to services in higher weighted DRGs if compression of weights is found to be a problem.[2]

HSRV also fails to take into consideration legitimate variation in cost that occurs between hospitals. Any hospital-level variation in cost that is not explained by the PPS case mix index is simply ignored. To the extent that certain services are provided most frequently in hospitals with higher average cost, the HSRV methodology will result in inappropriately lower DRG weights for these services.

If CMS wishes to remove sources of cost variation in DRG weights beyond its current process of standardization, the process could be expanded to include factors other than wage index, indirect teaching, and disproportionate share. This could lead to more precise and valid cross-hospital adjustments in costs than are provided with the broad, undiscerning approach of HSRV.

Based on these concerns with HSRVcc, we believe conversion to a system of traditional cost-based weights – without HSRV – is the most appropriate way to increase the accuracy of the payment system. Initial analyses by hospital groups suggest that converting to traditional outpatient-style cost weights in IPPS may have the largest effect on improving the accuracy of the DRG payment system.[3]

- **Adjusting for Charge Compression Is a Critical Component of Any Cost-Based Weights. Medtronic Is Submitting a Reasonable and Robust Solution to Address the Issue of Charge Compression for Implantable Devices.**

Though we believe adopting traditional cost-based weights is the most appropriate way to improve payment accuracy in the inpatient payment system (as measured by matching payments to cost), we have significant experience with cost-based weights in the outpatient system that suggests important improvements are necessary to ensure that cost-based weights accurately reflect the cost and weights of advanced implantable therapies.

Medtronic has worked with CMS for the past six years regarding concerns about inaccurate estimates of costs in OPPS. Median cost data for certain therapies, including high cost implantable devices, have been thousands of dollars lower than actual hospital acquisition costs as demonstrated by multiple sources of third-party data. CMS has needed to use external data and payment floors in an attempt to arrive at more accurate payment rates.

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[2] Grace M. Carter and Jeannette A. Rogowski, "How recalibration method, pricing, and coding affect DRG weights," Health Care Financing Review, winter 1992, Vol. 14, No. 2, pp. 83-96.

[3] The Health Economics and Outcomes Research Institute of the Greater New York Hospital Association.

We have done extensive research to understand the reasons why the cost data do not accurately represent the actual costs of implantable technologies. Our analyses have found that one of the most important shortcomings in the OPPS methodology is that it does not include any mechanism to address the known phenomenon of charge compression.

Charge compression occurs when hospitals use a lower percentage mark-up for higher cost items while CMS uses a single cost-to-charge ratio (CCR) for the many items and services in a single department. Methodologies that rely on uniform CCRs underestimate the cost of more expensive items and overestimate the cost of less expensive ones, resulting in a systematic distortion of the estimated costs and of the resulting cost-based prospective payment rates. In Attachments 3 and 4, we are submitting two of the latest analyses that document the existence and effect of charge compression on payment rates for services involving implantable therapies.

Although evidence of the effect of charge compression is not new, research supporting an adjustment to offset charge compression was not previously available. We believe an analysis completed during the comment period presents a viable solution. The analysis takes advantage of the detailed coding of supplies charges by revenue center on Medicare claims data to split the single cost-report CCR for supplies and equipment into separate CCRs for each supplies sub-category. Five supplies sub-categories are used: general supplies, implantables, sterile supplies, pacemakers (and defibrillators), and all other supplies. The division is based on a strong statistical association between the mix of supplies charges (by revenue center) in a hospital and the overall supplies CCR in a hospital.

By pooling the information from all hospitals, a regression analysis yielded a single set of CCR adjustments that reflect national average CCRs for each of the five supplies sub-categories. This national-average set of adjustments was then applied to each hospital (and combined with each hospital's actual supplies CCR), resulting in an adjusted estimate of cost on each MedPAR record.

The analysis found a strong, statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's overall average CCR for supplies. For example, hospitals with a higher share of charges in the pacemaker and implantable device revenue centers (0275, 0278) have higher supplies CCRs.

CMS could use the coefficients from this regression model to develop a data-driven adjustment for creating CCRs for sub-categories of supplies. We are submitting detail on the specific methodology of the charge compression adjustment in Attachments 4 and 5. Using the available MedPAR data, only four of the supplies sub-categories have enough charges, on average, to allow such a statistical estimate, making implementation easy while clearly improving accuracy.

The research found, on net after all budget-neutrality adjustments, the average CCRs for the supplies sub-categories which are shown in the table below. The average CCR for all supplies together was 0.33 (top line), but the regression analysis showed substantial variation in CCR by category. The pacemaker category (which also includes hospital charges for a significant portion of defibrillators) has an estimated CCR of 0.46 (or just slightly more than a 100 percent average

mark-up, calculated by taking 1/CCR). The category of general supplies, by contrast, has an estimated CCR of 0.24 (or just over a 300 percent average mark-up).

Estimated CCRs for Supplies Sub-Categories	
Supplies subcategory	Net average CCR after Budget-neutrality adjustment
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29
Source: Direct Research, Ltd. analysis of 2004 5% standard analytic file and hospital cost report data. May 2006.	

The research showed that this variation in CCRs across sub-categories has a significant impact on supply-intensive DRG weights. Cost-based DRG weights would increase for DRGs with substantial charges in the implantable devices and pacemaker/defibrillator revenue centers.

In generating the supplies sub-category CCRs, budget neutrality was maintained in each hospital by first "standardizing" each hospital's CCR. After creation of the sub-category CCRs, total supply/device costs in each hospital were made to match exactly total supply/device costs before any adjustments. The detailed (sub-category) CCR data for each hospital kept the hospital aggregate data unchanged (total supply/device costs matched the existing hospital total).

Medtronic strongly believes that any change toward cost-based weights, whether accompanied by the hospital relative value methodology or not, must address the distortion caused by charge compression. The analysis above demonstrates that such an adjustment is possible and provides a solid analytical basis for a specific adjustment. This adjustment should also be used to address charge compression in OPPS.

- **Improve the Use and Accuracy of Information from Hospital Cost Reports in Setting Cost-Based Weights**

In addition to adjusting for charge compression, alternative methods and data must be identified to improve the accuracy of hospital cost identification under a prospective payment system. The underlying goal of the PPS – and of each methodology to set payment weights – has always been to match payments to costs as accurately as possible. The key obstacle toward this goal, however, is the fact that data on the actual costs of providing care under a DRG payment system are not available.

The Medicare cost reports – which were instituted with the inception of the Medicare program in 1965 – contain information on the aggregate costs of providing care in a hospital, but they do not have the accuracy or specificity to match costs to individual services or items furnished to

patients or covered under specific DRGs. The Medicare cost reports were never designed or intended to be used to create procedure-specific payment rates.

As an important part of moving to cost-based weights, CMS should convene a panel of experts to identify methods to better use or improve information in hospital cost reports for appropriate use in the inpatient and outpatient PPS weight-setting processes. The panel should be charged with reporting back on recommendations by March 2007, when CMS could consider the recommendations in coordination with the FY 2008 payment rule cycle.

In Attachment 6, we are submitting a paper that describes shortcomings with the accuracy of cost reports and cost-based weights and includes options that could be taken into consideration by the expert panel in determining ways to better use or improve information from hospital cost reports in setting cost-based weights.

- **Develop Severity-Adjusted DRGs Using the Existing CMS DRG System**

CMS is proposing to implement consolidated severity adjusted DRGs by FY 2008. The goal of severity-adjusted DRGs is to match higher payments to the most expensive-to-treat patients. A fundamental problem with the consolidated severity DRGs proposed by CMS is that they are based on a proprietary APR-DRG system that does not reflect changes made to the Medicare DRG system over the past two decades.

The use of APR-DRGs as the starting point for a severity-based DRG system results in numerous DRG mismatches and abrupt, inappropriate payment shifts unrelated to the goal of matching higher payments to more severe (i.e., higher comorbidity) patients in the current DRG system. (Attachment 7 includes a table showing some of the mismatches between the Medicare DRGs and APR-DRGs.)

In addition, the APR-DRG system does not currently include any method for recognizing technologies that represent increased complexity, but not necessarily greater severity of illness. This is a significant shortcoming in the current proposal.

Rather than use APR-DRGs, CMS should use the existing Medicare DRGs as the starting point for any severity-related changes. CMS could develop severity levels within all of the existing DRGs (or pairs of DRGs, in cases where CC or MCV splits now exist), or identify specific DRGs that may be most appropriate for severity adjustments.

We note that a recent hospital group analysis suggests that the severity DRGs proposed by CMS do not increase the overall payment accuracy of the DRG system.[4] Before implementing severity-DRGs, CMS should undertake an analysis to determine if adjusting the DRGs based on severity truly in fact increases the accuracy of the payment system.

[4] The Health Economics and Outcomes Research Institute of the Greater New York Hospital Association

- **Phase-In New DRG Methodologies to Assure Smooth Transition for Hospitals**

Cost-based weights and severity-adjusted DRGs must be implemented together to limit sharp fluctuations in payments to hospitals from year to year. A transition period is necessary to assure payment levels remain smooth and predictable as the reforms are implemented. As noted above, we do not believe cost-based weights and severity DRGs can be implemented in FY 2007 given the range and magnitude of issues in the proposed rule. Assuming all issues can be addressed, the transition to the new DRGs should begin in FY 2008.

Severity-adjusted DRGs (if determined to improve overall payment accuracy) should be instituted fully in FY 2008, and cost-based weights should be phased in over at least a three-year period during which an increasing blend of charge- and cost-based weights would be implemented, culminating with full cost-based weights no earlier than FY 2010.

Adjustments for charge compression should accompany any transition to cost-based weights and improvements in the use and accuracy of cost reports should be developed and implemented during the transition period to ensure that the accuracy of the cost data used to set weights improves throughout the transition period.

- **HSRVcc Methodology in Proposed Rule Raises Fundamental Questions About Accuracy. CMS Must Assure New DRG Weight-Setting Approaches Accomplish Goal of Payment Accuracy.**

As noted above, CMS' proposed HSRVcc approach raises serious methodological and policy concerns and appears to result in significant inaccuracies in payment rates for specific procedures. Initial analyses by hospital groups suggest that the impact of the HSRVcc methodology is substantially different than the MedPAC recommendations, and the methodology may even *decrease* payment accuracy relative to current charge-based weights.[5]

One of the procedures most severely affected by the HSRVcc methodology is insertion of implantable cardioverter defibrillator (ICD). The methodology reduces relative weights for the three major ICD DRGs (515, 535, and 536) by 25 percent or more. While the proposed reductions in the defibrillator DRGs imply that weights based on the existing charge-based methodology grossly overstate the costs of ICD procedures and therefore overpay them, a number of sources and analyses suggest that precisely the opposite is true:

1. In its report on physician-owned specialty hospitals, MedPAC found ICD procedures to have "lower marginal" profitability or "possibly a loss" for hospitals, based on calculation of payment-to-cost ratios and surveys of specialty hospital operators.[6]

[5] The Health Economics and Outcomes Research Institute of the Greater New York Hospital Association.

[6] Medicare Payment Advisory Commission, "Report to the Congress, Physician-Owned Specialty Hospitals," March 2005. See pages 21-23 for references to and 74-75.

2. Medtronic commissioned an analysis of total payments and costs per discharge under the current weight-setting system in 22 hospitals with sophisticated cost accounting systems that provide greater procedure-level cost accuracy and detail than can be determined through cost reports and the conversion of charges to costs via application of cost-to-charge ratios. The analysis found that average payments fell short of average costs ranging from 11 to 22 percent for ICD DRGs (and from 17 to 31 percent for pacemaker implants).[7]

3. An analysis matching FY 2004 charges from MedPAR to cost findings and cost-to-charge ratios from FY 2004 found that FY 2004 payments for DRG 515 – the largest volume DRG for ICD implants – fell short of estimated costs by 1 percent. While payments appeared to exceed estimated average costs by small amounts in DRGs 535 and 536, the cost estimates include the effects of charge compression, which disproportionately lower the estimated costs of procedures with implantable devices. Thus, it may be likely that costs did in fact exceed payments in DRGs 535 and 536, and that the extent of the shortfall in DRG 515 was greater than estimated.[8] The analysis, performed by Henry Miller, Ph.D., of Navigant Consulting, is included in Attachment 8.

4. CMS approved a new-technology add-on payment in FY 2005 for CRT-D, a sophisticated defibrillator device paid in the ICD DRGs that combines the benefits of cardiac resynchronization therapy with defibrillation. CMS found CRT-D to be inadequately paid in DRGs 515, 535, and 536 and granted the add-on payment to defray the costs of the therapy in these DRGs.

Given that payment rates under the existing charge-based methodology appear to be inadequate for ICD (and pacemaker) procedures to begin with, we believe the severe reductions proposed under HSRVcc are unjustified and provide a clear indication that the proposed HSRVcc methodology has major flaws and does not accomplish the goal of improving payment accuracy.

Medtronic fully supports the goal of improving payment accuracy, but there must be reliable indicators to demonstrate whether the goal of payment accuracy is actually achieved. We ask CMS to produce and publish careful DRG by DRG estimates of payment-to-cost ratios and relative profitability to determine the effectiveness of different weight-setting and patient classification methodologies in improving overall payment accuracy. Furthermore, as has been noted by many

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[7] See Attachment 6 for paper prepared for Medtronic, Inc. and St. Jude Medical, Inc. by Henry Miller, Ph.D., Navigant Consulting, "Issues in the Use of Medicare Cost Reports to Calculate DRG Relative Weights," June 5, 2006.

[8] The Health Economics and Outcomes Research Institute of the Greater New York Hospital Association found in its June 12, 2006 comment that ICD DRGs had positive cost margins in the range of 10-11 percent. The paper, however, noted specific issues in the identification of costs for higher cost implantable items. The paper indicated that, according to hospital finance executives, "...there was an exaggerated perception about the profitability of cardiac and orthopedic surgery cases because the cost of high-technology devices is greatly understated in the cost reports of many hospitals. They painstakingly educated us about the reasons for this, which have to do with the fact that the cost report instructions have not been updated to reflect developments in procurement practices for expensive items." Thus, Medtronic believes the GNYHA's findings on the cost margins for ICD DRGs may be overstated because they do not account for the issue of charge compression.

parties, these estimates must be adjusted to account for the fact that the cost of providing services that include high-technology devices are understated in the cost reports of many hospitals. We look forward to working with CMS to ensure that subsequent payment methodologies under consideration to reform the DRG system achieve the desired payment accuracy results.

- **Additional Product Specific Issues in the Proposed Rule**

Medtronic appreciates and agrees with the continuation of the new-technology add-on payment for the Restore rechargeable neurostimulator. With the conclusion of the new-technology add-on payment for the Kinetra dual-array neurostimulator used in the treatment of Parkinson's disease, we would like to thank CMS for its efforts to grant the add-on payment the past two years.

Medtronic did submit a proposal to reassign Kinetra from DRGs 001-002 to the more clinically and cost coherent DRG 543. While on average the charges associated with Kinetra procedures are significantly more consistent with the charges in DRG 543 than DRGs 001-002, CMS rejected the proposed reassignment on the basis that it believed the charges associated with the device (and thus the overall procedure) might be marked up excessively, and because it wanted to postpone resolution of the issue until the consolidated severity-adjusted DRG system was implemented.

We disagree with CMS' statements that mark-ups associated with Kinetra may overstate the total charges of the implant procedure. We are submitting information on charge compression in this letter (Attachments 3 and 4) that we believe conclusively finds that hospital charge mark-ups for implantable devices are in fact significantly lower than for other, lower cost supplies and equipment. (Based on this finding, we are submitting a proposal that would make adjustments to correct for the impact of charge compression in the setting of cost-based weights.)

We therefore believe that, if anything, the total charges found in MedPAR associated with Kinetra implant procedures may be understated relative to other procedures in DRGs 543, 001, and 002, and that the reassignment of the technology to DRG 543 is fully warranted. Given that we are recommending deferral of the implementation of the consolidated severity DRGs until at least FY 2008, we believe the CS-DRGs should not be a factor in CMS's decision to make DRG reassignments this year. We strongly encourage CMS to reclassify the Kinetra procedure – determined by CMS to be a significant clinical improvement over previous therapy for Parkinson's disease – to the more appropriate DRG 543.

Medtronic appreciates the issuance and DRG assignment of new ICD-9-CM procedures codes for the intracardiac hemodynamic monitor and implantable pressure sensing leads, also known as Chronicle. We also appreciate the clarification of codes for electrophysiological studies and non-invasive programmed stimulation, and agree with the proposal to add epicardial leads to the DRG logic so that all defibrillator devices and lead combinations are mapped to the appropriate DRGs.

Attachment 9 provides additional detail on our DRG reclassification, ICD-9-CM procedure code classification, and new technology issues.

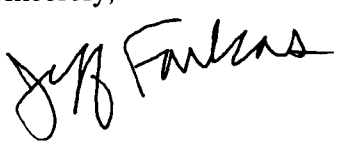
- **Conclusion**

The scope and magnitude of the task faced by CMS to reform the DRG system is enormous. Given the range of issues, potential impact on patient access to care, methodological concerns, and the external empirical analyses and benchmarks that call into question the accuracy of many of the proposed rates, we believe there is much more work to be done to ensure validity of the current proposals before implementation.

Medtronic fully supports the goal of improving payment accuracy, and ultimately believes a move to cost-based weights combined with an adjustment for charge compression is an appropriate path to take, but additional analysis and opportunity for stakeholder review are necessary before such changes can be instituted.

We appreciate the opportunity to comment on the F2007 proposed rule and would welcome the opportunity to work with CMS further on the development of appropriate reforms to the DRG system.

Sincerely,



Jeff Farkas
Senior Director
Health Policy and Payment

Attachments (9)

ATTACHMENTS TO MEDTRONIC COMMENT ON FY 2007 PROPOSED HOSPITAL INPATIENT RULE

1. Detailed Analysis of Methodological Flaws in HSRVcc Computations
2. May 9, 2006 Device Company Presentation to CMS on Issues in Proposed Rule
3. Analysis Benchmarking Charge Mark-Ups Found in OPPS to External Data on Costs
4. Analysis and Proposed Charge Compression Adjustment
5. June 7, 2006 Device Company Presentation to CMS on Charge Compression
6. Issues in the Use of Medicare Cost Reports to Calculate DRG Relative Weights
7. Table on DRG and CS-DRG Mismatches
8. Analysis of FY 2004 Payment to Cost Ratios for ICD and Pacemaker DRGs
9. Materials on Medtronic Product-Specific DRG & Code Issues in Proposed Rule

Attachment 175

ATTACHMENT 1

Detailed Analysis of Methodological Flaws in HSRVcc Computations

Memorandum:

To: IPPS 2007 Proposed Rule analysis clients
From: Christopher Hogan, Direct Research, LLC
Subject: CMS IPPS 2007 Proposed Rule analysis, revised
Date: Revised 6/9/06

In this memo I:

- Describe and discuss CMS' proposed methods.
- Model the CMS method, including the impact of the full proposal with "modified severity" DRGs.
- Provide a full explanation of the national cost-to-charge ratio issue, demonstrate that CMS's numbers are grossly in error, and illustrate what would happen if they were fixed.

1 EXECUTIVE SUMMARY

Purely technical issues in replicating CMS methods:

- I walked through the weight estimation using both the 2004 and 2005 files. For 2004, where CMS published the record count in the rule, I end up with the right number of records.
  - CMS gets 11.14 million
  - I get 11.12 million
- I believe there are two purely technical errors in the CMS numbers.
  - CMS failed to strip the organ acquisition charges off the records. This inflates the CMS published weight for organ transplant and hides the cuts that will occur for transplants. It may cause small discrepancies elsewhere.
  - I believe CMS improperly dropped 3% of records because the hospital fiscal year had 366 days due to leap year (ie., they required a 365 day year). I don't think this matters.

The CMS estimate of national cost-to-charge ratios and cost shares by revenue center.

- As a matter of arithmetic, if you want to estimate US total costs based on US total charges for a service, you must use the charge-weighted national average CCR. By average, I mean the arithmetic mean.
- CMS uses hospital-weighted geometric mean CCR, after trims.
- This is not correct algebraically, and is not even close to correct empirically.
- In addition, CMS's approach to calculating the CCRs throws out hospitals with CCR for routine days below 0.26. But in fact, those CCRs appear real, they apply mostly to a few hundred very large hospitals, and those hospitals contributed roughly one-quarter of all routine day charges.
- The hospital-weighting instead of charge weighting, along with the impact of the trim, creates a large mismatch between the charges CMS uses in the overall calculation (all charges) and the CCRs that CMS then applies to those charges.

- The primary issue is the hospital-weighting. Fixing the trim alone, while retaining hospital-weighted averages, would not generate correct CCR values.
- Fixing this problem by using charge-weighted CCRs would substantially reduce the redistributions shown in the proposed rule.

To do MedPAC-style cost weights, you need CCRs for all hospitals for all charge categories. You have to impute values where they are missing. It does not appear difficult to impute missing CCR data, using CMS's ten charge categories.

- I imposed a simple imputation for the 10 CCRs in each hospital. First, I calculated how the hospital compared to the average. For the CCRs that a hospital had, I took the average ratio between the hospital CCR and the national average. Then, where a CCR was missing, I multiplied the national average CCR for that category, times this ratio. So, for example, if a hospital CCRs averaged 80% of the US norms for the CCRs that were present, I assumed they would have averaged 80% of US norms for the CCRs that were missing, and gap-filled the missing CCRs according.
- The charge-weighted US average CCRs were essentially unchanged by this. This happens largely because, for each charge category, hospitals that have CCRs account for nearly all of charges anyway. So, on a charge-weighted basis, there really are not that many missing CCR values to begin with.

2 NOTES ON MODELING THE CMS METHODS.

2.1 Making sense of the two separate discussions of methods.

CMS discusses method in two different sections of the proposed rule, circa page 60 and circa page 190. The methods descriptions do not entirely agree. The earlier description, for example, discusses the need to get rid of all-inclusive rate provides, but not the later section. The later section mentions that cancer hospitals, children's hospitals, and religious nonmedical facilities must be removed. The earlier section gives exact record counts -- but for a version of 2004 MedPAR. The later section gives only a single record count that does not match the final distributed version of 2005 MedPAR (and likely refers to the December update of the MedPAR, not the update distributed with the rule.)

I used both sections, and both CMS-supplied files, to work through the methods that CMS used. CMS supplied a version of 2004 MedPAR with the consolidated severity DRGs, and supplied the standard 2005 MedPAR. I used the 2004 MedPAR (where CMS published an exact record count after edits) to determine what CMS did, then ran the analysis on the 2005 file.

2.2 Screening the file.

- Start from FY 2005 MedPAR (no consolidated severity DRG).
- Drop records that are HMO no-pay bills
- Drop records that are not from short-term hospital or not PPS discharges (e.g., drop long-term care hospitals, drop discharges from PPS-exempt hospital units). I did this using the facility type and PPS flags on the MedPAR records themselves.
- Drop hospitals not paid under IPPS: CAH, LTCH, IRF, cancer, children's, psychiatric, religious nonmedical (Christian Science sanatoria), Indian Health Service hospitals, and hospitals in Maryland. I dropped many of these using the March 2005 Provider of Services file. Ideally, I would have used a more recent POS file to do that, but this should have a negligible impact on the results.
- CMS eliminates transplant cases outside of approved transplant centers, but I did not do this. Because CMS will not pay for transplants outside approved centers, this probably has a negligible effect on results.
- Subtract organ acquisition charges from total charges. (In the results section, I note that CMS appears to have failed to do this.)
- Drop hospitals with no cost report data. To match the CMS published number for the 2004 file, I used all cost reports (as-submitted, closed, re-opened). I determined the "FY 2003" cost report based on the greatest overlap between the hospital fiscal year and Federal fiscal year 2003. CMS says that they dropped reports with fewer than 365 days, but I believe they dropped reports with fewer than or more than 365 days, which includes 3% of discharges for hospitals with a 366 day fiscal year due to Feb 29 2004.
- Claims with total charges or total length of stay less than or equal to zero were dropped.

- Claims that had an amount in the total charge field that differed by more or less than $10 from the sum of charges for routine days, intensive care, pharmacy, special equipment, therapy, operating room, cardiology, laboratory, radiology, and other services were deleted. I believe this mean that professional services charges were reported on the claim (the only MedPAR charge category not discussed in the CMS regulations), then the claim was dropped.
- All-inclusive rate providers must be dropped. These are hospitals that put all charges into the accommodations (per-diem) field. For all-inclusive providers, not only did I eliminate records with just day charges on them, but I also I scanned the 2004 five percent sample file SAF for hospitals that ever billed under the all-inclusive rate revenue center codes (0100, 0101). There were 237 such hospitals. I excluded all of them.
- I also dropped providers who did not bill for at least eight of the 10 CMS revenue center clusters. This should also eliminate the all-inclusive rate providers.
- On the 2004 file, CMS ended with 11.14 cases, I ended with 11.12.
- Calculate a case-weight for each DRG based on CMS transfer and post-acute transfer policy.
- Trim the file for statistical outliers based on 2006 DRGs. Outliers must be outliers in both total charges and charge per day.
- For the 2005 file, after all drops and trims, I had 11.05 million records.

2.3 Modeling the rates.

CMS methods can be summarized as follows. An in-depth discussion of the cost-to-charge ratios is given in a separate section.

- Divide the claim into ten pieces -- the ten revenue center clusters.
- Treat each of those pieces separately, and estimate a set of charge-based DRG weights for each piece separately.
- For example, take routine accommodation charges.
    - A: Calculate the average charge per discharge, separately for each hospital.
    - B: Calculate it again, for every DRG in every hospital.
    - Divide B/A to get a *hospital-specific* relative weight, for that DRG, in that hospital.
    - Note that the (discharge-weighted) average hospital-specific DRG relative weight, in each hospital, is 1.0, by construction.
    - But you don't want each hospital to have an average of 1.0. Under the HSRV method, you want each hospital to have an average that is exactly where the hospital's case mix predicts its average ought to be.
    - So, average up all those DRG weights (discharge-weighted) across the entire dataset to get *national average* DRG weights. These average to 1.0 by construction.
    - Use these *national average* DRG weights to calculate a case-mix index for each hospital (ie., what is the mean value of the *national average* DRG weight for all cases in that hospital?). Call that the CMI value for the hospital.

- Re-set *the hospital-specific* DRG weights so that the hospital's average, for those *hospital-specific* DRG weights, is exactly equal to the CMI value for the hospital. (Literally, you multiply them all by the hospital's CMI value).
- But now, if you took national averages, you'd get a slightly different set of national average DRG weights, because you've re-weighted the hospitals.. That's fine. Do that, recalculate the CMI values, re-weight the hospital-specific DRG weights, and repeat until the national average DRG weights stop changing from one iteration to the next.
- (In fact, however, this routine can settle into a state where the weights just continue to make minuscule changes back and forth between rounds, without settling down to an absolutely final set of weights.. At which point, you stop the iteration and use the weights.)
- The end result is a set of DRG weights that are exactly equivalent to the following:
  - 1: Each hospital's average charges (after re-weighting) are exactly equal to the average charge you would expect, based on that hospital's DRG mix alone.
  - 2: The DRG relative weights are the averages of the hospital data, after you have re-weighted them to make 1: above true.

- The bottom line is that all variation in charges is ignored, except the variation in charges that is predicted by the hospital's DRG mix.
- After you've done this separately for the 10 revenue center clusters, you have ten sets of DRG weights, each of which (by construction) averages 1.0 for the entire data set.
- To arrive at the total DRG weight, let each of these contribute to the overall weight in proportion to the estimated national average share of costs, for all discharges, attributed to those ten revenue center clusters. So, for example, if routine accommodation costs account for 25% of total costs, then the routine accommodation weight counts for 25% of the total DRG weight in each DRG.
- Technical trick: Although CMS discusses the process in terms of iterating over the entire 11-million-record file, in fact you can do the arithmetically identical calculation using two summary files: one by hospital and DRG, and one by hospital. This vastly speeds up the calculation process.

2.8 Two technical errors in CMS's analysis, neither of which affects key DRGs significantly.

2.8.1 CMS forgot to remove transplant charges from the claims. This has the effect of masking the rate reductions that will occur for transplant surgery.

Compare the CMS 2006 and 2007 weights for any of the organ transplants (e.g, kidney transplant) and you will see that the relative weight went up, in some cases by quite a bit. I didn't find that. A bit of inspection shows that the rate increase is almost directly proportional to the fraction of charges that are for organ acquisition. But that's a pass-through cost, those charges should have been removed from the claims, and CMS clearly didn't do that.

2.8.2 I believe CMS forgot about leap year, and tossed 3% of claims solely because some hospital cost report periods extended over Feb 29, 2004.

The only way I got my 2004 claim count (11.13 million) to match CMS (11.14 million) was to drop all hospitals where the cost report period was anything other than exactly 365 days. CMS says they dropped all with a period of less than 365, but did not mention dropping those over 365.

The problem is that hospitals choose their own fiscal year. So, what is "the 2003" cost report for a hospital? The traditional method of matching cost reports to claims is to take the hospital cost report that has the greatest overlap with the Federal Fiscal Year in question. So, in some cases, "the 2003" hospital cost report was one that ran (e.g.) from 3/1/03 to 2/29/04, or 366 days. If I don't drop those, I end up with 300,000 too many claims. Either CMS dropped these, or it's a coincidence that I got that close to the CMS claims count.

3 THE CMS CCRS

3.1 The math for calculating the correct national average CCR.

This section shows, using algebra, that to get from total national charges to total national costs, you must multiply by the charge-weighted national average cost-to-charge ratio. To the extent that CMS's CCRs differ from that, they do not provide a correct estimate of total national costs.

Take routine costs for example. Let H subscript hospitals, let Σ_H mean the sum across all hospitals, let Charges be the charges for routine days, and let Cost be the cost for routine days. Then:

- Cost at a hospital is charges times that hospital's CCR:
  $Cost_{(H)} = Charges_{(H)} * CCR_{(H)}$

- Total US cost or total US charges is the sum of that, across all hospitals:
  $Cost_{(US)} = \Sigma_H\{Cost_{(H)}\}$
  $Charges_{(US)} = \Sigma_H\{Charges_{(H)}\}$

- Substitute Charges x CCR for cost (algebra)
  $Cost_{(US)} = \Sigma_H\{ \quad Cost_{(H)} \quad \}$
  $Cost_{(US)} = \Sigma_H\{Charges_{(H)} * CCR_{(H)}\}$

- Algebra: multiply by 1, in the form of total US charges divided by total US charges. You'll see the point of this in the next line.
  $Cost_{(US)} = [\quad 1 \quad]* \Sigma_H\{Charges_{(H)} * CCR_{(H)}\}$
  $Cost_{(US)} = [\Sigma_H\{Charges_{(H)}\}/ \Sigma_H\{Charges_{(H)}\}]* \Sigma_H\{Charges_{(H)} * CCR_{(H)}\}$

- Re-arrange the terms (commutative law)
  $Cost_{(US)} = \Sigma_H\{Charges_{(H)}\}*[\Sigma_H\{Charges_{(H)} * CCR_{(H)}\}/ \Sigma_H\{Charges_{(H)}\}]$

- The term on the far right is the definition of the charge-weighted cost-to-charge ratio.

So, the final equation says: Total US cost for a service is the product of total US charges for that service times the charge-weighted US average cost-to-charge ratio for that service. Conclusion: **To get from total US charges to total US cost, you must multiply by the charge-weighted US average CCR.** That's not a policy decision or a methods option, that's just algebra.

Possible exceptions: The only exceptions occur if you can, by chance, get CCR values that closely approximate the correct, charge-weighted US average CCRs. So, you'll get answers that are close to correct if:

- You can find an approximation that very nearly gives you the charge-weighed national average CCR. (But to know that it's near, you'd have to calculate the charge-weighted average anyway).
- Because you are using this only to calculate charge shares, if you can find an approximation that reduces or inflates all the CCRs by the same factor, then that would be good enough. Absolute dollar costs would be wrong, but the cost shares would be correct.

3.2 How far off are the CMS numbers from national average charge weighted CCRs?

My contention is that the CMS CCRs fit neither of these exceptions. They are not close to the correct charge-weighted national average CCRs, and they are not off by any uniform factor across the charge categories.

I calculated national averages with trimming by removing the top and bottom 2.5% of CCRs, for each charge category, on a charge-weighted basis. Then I calculated a charge-weighted national average. The table below tells the entire story. The correctly-calculated charge-weighted data are vastly different from the CMS estimates.

Table 1: National Cost-to-Charge Ratio Estimates

	Incorrect	Incorrect	Incorrect	Correct
MedPAR Charge Grouping	**CMS, CCR factor file**	**CMS, published in proposed rule**	**Calculated using CMS methods**	**Charge-weighed arithmetic average**
Routine Days	0.84	0.85	0.87	0.55
Intensive Days	0.71	0.72	0.73	0.48
Supplies & Equipment	0.33	0.34	0.34	0.33
Therapuetic Services	0.35	0.35	0.36	0.29
Laboratory	0.25	0.25	0.26	0.20
Radiology	0.24	0.24	0.25	0.21
Other Services	0.50	0.51	0.52	0.46
Drugs	0.25	0.37	0.26	0.22
Operating Room	0.36	0.26	0.38	0.32
Cardiology	0.18	0.20	0.20	0.21
Memo: Ratio Routine to Cardiology CCR	4.78	4.25	4.28	2.57

Source: Analysis of FY 2003 cost reports matched to summarized FY 2005 MedPAR proposed rule data

The CMS CCRs imply an implausibly high level of total costs (Table 2). This can be shown by summing charges on the edited MedPAR, calculating total estimated cost (with

2003 CCRs applied to 2005 charges). Then, this crude cost estimate is approximately adjusted for the effects of charge and cost inflation between the 2003 cost report and and the 2005 claims, and compared to actual CMS 2005 payment (excluding pass-throughs).

Under the assumption that charges have been rising 7 percent per year and costs have been rising 2.5 percent year per year, the raw 2005 cost estimate needs to be multiplied by a factor of 0.92 to estimate actual 2005 costs. (Because charges are rising faster than costs, the projected actual 2005 CCRs would be 92% of the 2003 CCRs, based on the assumptions above. This adjustment projects the 2005 CCRs and applies them to the 2005 charge data.) After this adjustment, we see that the payment-to-cost ratio implied by the CMS CCRs is 0.81, implying implausibly large losses on Medicare inpatient claims. The charge-weighted CCRs, by contrast, imply a roughly 2 percent positive Medicare inpatient margin for 2005. Clearly, the charge-trimmed, charge-weighted CCRs provide a more realistic estimate of total costs.

Table 2: Costs and Margins Implied by CMS CCRs and Charge-Weighted CCRs

		Charge-Weighted CCRs				CMS CCRS		
Charge Category	Total Charges	Charge-Weighted CCR	Estimated cost	Resulting cost share		CMS CCRs	Estimated cost	Estimated cost share
routine	$ 46.5	0.552	$ 25.7	24.0%		0.836	$ 38.9	28.9%
icuccu	$ 36.4	0.482	$ 17.5	16.4%		0.714	$ 26.0	19.3%
supplies	$ 46.1	0.330	$ 15.2	14.2%		0.334	$ 15.4	11.5%
therapy	$ 14.9	0.292	$ 4.4	4.1%		0.345	$ 5.1	3.8%
laboratory	$ 35.8	0.200	$ 7.2	6.7%		0.251	$ 9.0	6.7%
radiology	$ 24.2	0.214	$ 5.2	4.9%		0.239	$ 5.8	4.3%
other	$ 16.6	0.464	$ 7.7	7.2%		0.499	$ 8.3	6.2%
pharmacy	$ 46.2	0.223	$ 10.3	9.6%		0.254	$ 11.7	8.7%
operating	$ 30.2	0.321	$ 9.7	9.1%		0.363	$ 11.0	8.2%
cardiology	$ 18.5	0.215	$ 4.0	3.7%		0.175	$ 3.2	2.4%
Total	$ 315.4		$ 106.8	100.0%			$134.4	100.0%
Assumptions for Adjustment to 2005 basis								
Annual charge infl 2003-2005			7.0%				7.0%	
Annual cost infl 2003-2005			2.5%				2.5%	
Resulting adjustment to CCRs			0.92				0.92	
Estimated cost, all-2005 basis			$ 98.0				$123.3	
Total payment on edited file			$ 100.2				$100.2	
Payment-to-cost ratio			1.022				0.812	

Source: 2003 cost reports matched to 2005 MedPAR data. CMS CCRs taken from the CMS CCR weight file posted with the 2007 IPPS proposed rule

Finally, because the issue of the correct CCR appears to hinge on the routine and ICU/CCU costs, we can look in detail at routine costs to see what was and was not included in the CMS CCR cost estimate. The CMS CCR trims removed relatively few

hospitals. In particular, hospitals had to have a routine accommodation CCR of 0.26 or less to be trimmed out by the low end of the CMS statistical trim.

Table 3 shows the disproportionate effect that the CMS trim had on accommodations charges, and begins to explain why those CCRs were most strongly affected. In fact, more than a quarter of total routine charges were eliminated from the CCR calculation. The only way to calculate that is to match the cost reports to the claims and tabulate the fraction of charges that were trimmed.

Table 3: Percent of Charges, for Hospitals Eliminated in CMS CCR Trim

Cost category	Total charges on File	Charges after trim	Pct of charges trimmed
routine	$ 46.5	$ 34.1	27%
icuccu	$ 36.4	$ 28.8	21%
supplies	$ 46.1	$ 42.8	7%
therapy	$ 14.9	$ 13.8	7%
laboratory	$ 35.8	$ 32.5	9%
radiology	$ 24.2	$ 22.8	6%
other	$ 16.6	$ 16.0	3%
pharmacy	$ 46.2	$ 43.6	6%
operating	$ 30.2	$ 28.9	4%
cardiology	$ 18.5	$ 17.7	4%

Source: 2003 cost reports merged to 2005 MedPAR

Finally, Table 4 strongly suggests that the hospitals eliminated in the CMS trim were large and indeed had high accommodation CCRs. Although we have no independent source of cost data, for routine accommodation charges we can compare charge per day. Based on the charge per day, the hospitals eliminated by the trim appear as they though should have had a low CCR. All together, those hospitals accounted for more than one-quarter of all routine accommodation charges in the file.

Table 4: Routine Accommodation Charge Per Day

CMS CCR trim?	Hospitals	Charges, $B	Days, Millions	Charge per Day
Not Trimmed	3133	$ 34.11	39.1	$ 873
Trimmed	238	$ 12.37	3.3	$ 3,723
Total	3371	$ 46.48	42.4	$ 1,097

Source; 2003 cost reports matched to edited 2005 MedPAR file.
The CMS CCR trim category may also include a few hospitals that literally had no routine accommodation CCR on their cost report.

Taken as whole, the evidence suggests that:

- The correct arithmetic (algebra) requires the use of a charge-weighted national average cost-to-charge ratio.
- The CMS CCRs are vastly different from those charge-weighted CCRs.
- The difference is almost entirely in the accommodations CCRs, not the ancillaries.
- The hospitals trimmed from the calculation illustrate how the hospital-weighted averages could be so far off from the correct (charge-weighted) averages. The small fraction of *hospitals* that were trimmed from the calculation accounted for more than one-quarter of routine *charges*, and in fact had a high charge per day.
- Total costs projected with the CMS CCRs are implausibly high.

The result is that the CMS CCRs significantly distort the resulting relative values, compared to charge-trimmed, charge-weighted CCRs. They overstate the impact of accommodation costs and understate the impact of ancillaries. Table 6 shows the weights for a handful of DRGs that illustrate the impact of the CMS CCRs. The DRGs were chosen to illustrate the general finding that the CMS CCRs tend to exaggerate the change that would occur from charge-based to cost-based weights.

Table 5: Estimated DRG Weights Under Approaches, 2007 IPPS Proposed Rule									
Selected DRGs with Large Volumes and Large 2006-2007 Payment Changes									
2007 DRG	mdc	med-surg	title	Cases	2006 Wgt.	2007 prop. Wgt	% chng.	2007 prop, corrected CCRs	% chng.
125	05	MED	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DI	83,447	1.10	0.79	-28%	0.87	-20%
128	05	MED	DEEP VEIN THROMBOPHLEBITIS	3,907	0.70	0.89	27%	0.82	18%
236	08	MED	FRACTURES OF HIP & PELVIS	38,332	0.74	0.88	19%	0.83	12%
253	08	MED	FX, SPRN, STRN & DISL OF UPARM,LOWLEG EX FOOT AGE >17 W CC	22,734	0.78	0.91	17%	0.86	11%
277	09	MED	CELLULITIS AGE >17 W CC	108,959	0.87	1.00	15%	0.94	8%
294	10	MED	DIABETES AGE >35	88,404	0.77	0.86	13%	0.82	7%
430	19	MED	PSYCHOSES	63,619	0.65	1.23	90%	1.08	66%
521	20	MED	ALCOHOL/DRUG ABUSE OR DEPENDENCE W CC	27,014	0.69	0.92	32%	0.85	22%
522	20	MED	ALC/DRUG ABUSE OR DEPEND W REHABILITATION THERAPY W/O CC	3,357	0.48	1.06	121%	0.86	80%
515	05	SURG	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	52,903	5.52	4.15	-25%	4.90	-11%
557	05	SURG	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJO	111,726	2.87	2.13	-26%	2.45	-15%
Source: Analysis of edited 2005 MedPAR and CMS 2007 IPPS proposed rule									

ATTACHMENT 2

May 9, 2006 Device Company Presentation to CMS on Issues in Proposed Rule

Issues in CMS FY 2007 Hospital Inpatient Proposed Rule

Medtronic, Johnson & Johnson, Boston Scientific Meeting with CMS
May 9, 2006

Agenda

- Introductions
- CMS HSRVcc Proposal
  - Differences with Traditional Cost-Based Weights
  - Assumptions and Apparent Technical Errors
- General Issues with Cost-Based Weights & HSRV
- Consolidated Severity Adjusted DRGs
- Improvement of Cost Data Accuracy
- Next Steps/Recommendations

2

Improving Payment Accuracy

- MedPAC's recommendations on physician-owned specialty hospitals initiated an important national dialogue on improving the accuracy of DRG payments
- We fully support the goal of improving payment accuracy in the DRG system
  - Payments should match costs as closely as possibly
  - Inpatient procedures should be neither overpaid nor underpaid
- Impact of proposed changes and methodologies must be fully understood by all stakeholders

3

CMS HSRVcc Proposal

- Intermingles HSRV and cost-based weights
- Differs significantly with traditional cost-based weights
  - HSRVcc: Charge-based HSRV weights reduced to cost weights via application of national CCRs from 10 amalgamated cost centers
  - Traditional Cost Weights: Reduce all charges to estimated costs and then calculate weights (similar to MedPAC methodology in specialty hospital report)
- HSRVcc national CCRs exacerbate charge compression

4

CMS National CCR Calculation

- Cost weights require cost-to-charge ratios for 10 revenue centers.
- MedPAC approach to CCRs
  - Match claims to cost reports.
  - Calculate cost on each claim
  - Summarize to get DRG relative weights.
- CMS "shortcut" approach to CCRs:
  - Do not match claims to cost reports.
  - Trim and average CCRs from cost reports only.
  - CMS uses *hospital-weighted geometric average* CCRs
  - Then, 10 national CCRs x 10 US charge totals = 10 cost shares.
  - Use cost shares to generate final DRG relative wgt.

5

Problems with CMS National CCR Calculation

- CMS CCRs are arithmetically incorrect.
  - Accept MedPAC method as correct.
  - Use algebra to determine how CMS must calculate national average CCR (IF - THEN)
  - IF: total US charges x CCR = total US cost,
  - THEN: CCR = charge-weighted average of hospital CCRs (not hospital-weighted, not geometric mean).
- Empirically important mistake - next slides.

6

Simple Example Showing Correct and Incorrect Arithmetic

	Cost	=	CCR	*	Charges
Step 1: Three hospitals, $1 cost each, $3 total costs					
Hospital 1	$ 1.00	=	0.10	*	$ 10.00
Hospital 2	$ 1.00	=	1.00	*	$ 1.00
Hospital 3	$ 1.00	=	1.90	*	$ 0.53
Correct US total	**$ 3.00**		**??**		**$ 11.53**
Step 2: Calculate US Average CCR three ways					
Unwgtd mean			1.00		
Unwgtd geo mean			0.79		
Charge wgtd mean			0.26		
Step 3: Calculate US total cost from US charges * US CCR					
Total w/ unwgtd mean	$ 11.53	=	1.00	*	$ 11.53
Total w/ unwgtd geo mean	$ 9.06	=	0.79	*	$ 11.53
Total w/ charge wgtd mean	**$ 3.00**	=	**0.26**	*	**$ 11.53**

National Average CCRs, CMS Versus Charge-Weighted

Charge Grouping	**CMS, published**	Calculated, CMS methods	**Calculated, Charge-Weighted**
Routine Days	**0.85**	0.87	**0.55**
Intensive Days	**0.72**	0.73	**0.48**
Supplies & Equipment	**0.34**	0.34	**0.33**
Therapuetic Services	**0.35**	0.36	**0.29**
Laboratory	**0.25**	0.26	**0.20**
Radiology	**0.24**	0.25	**0.21**
Other Services	**0.51**	0.52	**0.46**
Drugs	**0.26**	0.26	**0.22**
Operating Room	**0.37**	0.38	**0.32**
Cardiology	**0.20**	0.20	**0.21**

CMS CCRs Yield Grossly Incorrect Total Costs

	With CMS CCRs	With Charge-Weighted CCRs
Total charges on File ($B)	$ 315	$ 315
Estimated raw cost (charges x CCRs, ten categories, $B)	$ 134	$ 107
Estimated 2005 cost (raw cost x 0.92 to account for 2003 CCR vs 2005 chgs, $B)	$ 123	$ 98
Actual 2005 payment on file, $B.	$ 100	$ 100
Estimated 2005 payment-to-cost ratio	**0.812**	**1.022**

9

Hospitals Trimmed out of Routine CCR Calculation Have High Charge Per Day

CMS excludes them from CCR calculation but includes them in charge totals for cost share calculation

CMS CCR trim?	Hospitals	Routine Charges, $B	Routine Days, Millions	Charge per Day
Not Trimmed	3,133	$34.11	39.1	$873
Trimmed	238	$12.37	3.3	$3,723
Total	3,371	$46.48	42.4	$1,097

10

Large Impact on DRG Weights

(MDC-Medsurg categories with largest gains and losses)

MDC	MDC title	Med or Surg	2005 PPS discharges	Payment change, CMS methods	Payment change with charge-weighted CCRs
19	Mental Diseases,Disorders	**MED**	112,111	64%	46%
05	Circulatory System	**SURG**	1,068,862	-16%	-9%

11

CMS CCR Values - Conclusion

- Several factors suggest CMS CCRs are wrong.
  - They are algebraically incorrect. Total US charges x charge-weighted CCR = total US cost.
  - CMS CCRs differ substantially from charge-weighted CCRs.
  - CMS CCRs imply large negative Medicare 2005 inpatient margin. Charge-weighted CCRS imply 2% positive margin.
  - CMS approach trims out hospitals with genuinely high routine charge per day, accounting for over one-quarter of routine charges. Those hospitals are excluded from CCR calculation but included in cost-share calculation.
- CMS CCRs substantially exaggerate the impact of moving to cost-based weights.
- Large negative impact on cardiovascular surgical procedures.

12

PPS Payment Trends: Last 5 and 10 Years

	Cumulative Change from 1996	Cumulative Change from 2001
Market Basket	36.5%	18.4%
PPS Update	25.6%	17.2%
Average Payment Per Case - All	32.7%	24.1%
Average Payment Per Case - Urban	27.9%	19.1%
Average Payment Per Case - Rural	53.7%	44.9%
Average Payment Per Case - Major Teaching	19.1%	14.0%

13

Impact of New DRG Weights

- Very significant redistribution
  - Trend is from large, urban and teaching to small, rural and non-teaching
  - And from complex or high tech to longer-stay cases
- Favors room and board cost centers over ancillaries
- Cardiology is hit particularly hard
- For many classes of hospitals, the proposed regulation is like a "MB minus" update

All Hospitals (3,522)	+.1%
Large Urban (1,391)	+.1%
Other Urban (1,126)	-.8%
Urban, at least 300 beds (580)	-1.1% to -1.5%
Rural (1,005)	+3.0%
Major Teaching (237)	-.9%

14

Issues Raised by HSRVcc

- Hospital-specific relativity may be questionable policy
  - Unnecessary change since current standardization policy adjusts for differences due to wage levels, teaching and disproportionate share
  - HSRV reduces the range of variation between low and high DRG weights
    - Long-time concern of PPS experts that this could deter access to complex care

15

Issues Raised by HSRVcc

- HSRV particularly disadvantages surgical cardiac care
  - Yet research found that losing hospitals surprisingly have lower charges for expensive cardiac care than winning hospitals
    - They lose because their overall charge levels are higher, but cardiac mark-up is less
    - A possible conclusion???: these hospitals should increase cardiology charges!

16

Issues Raised by Cost-Based Weights

Is payment accuracy increased?

- Accuracy and completeness of cost report
  - Provides aggregate costs at department (i.e., cost center) level
    - Costs of items, services and DRGs must be estimated
      - CMS uses charges from claims reduced by cost-to-charge ratios (CCRs)
      - CCRs are derived from individual hospital cost reports
    - Accounting and cost allocation practices vary substantially across hospitals
  - Cost report assumes uniform per diem rates for routine and special care days, yet experts believe these vary by DRG

17

Issues Raised by Cost-Based Weights

Is payment accuracy increased?

- Accuracy and completeness of cost report
  - 1993 ProPAC study found routine costs were overestimated by 12.6% and ancillary underestimated by 4.9%
    - Study concluded that …
      - *"The cost report's reliability is reduced considerably when routine inpatient costs and ancillary costs are analyzed separately."*
      - Cost report data *"are clearly not reliable or accurate for analyzing micro-level costs"*
  - 1988 ProPAC recommendation to use cost-based weights cited concern with cost report data
    - *"cost report data may, in some cases, produce imprecise DRG weights"*
    - *"Secretary should verify the accuracy of cost report data and implement changes as necessary"*

18

Issues Raised by Cost-Based Weights

Is payment accuracy increased?

- Only about 15% of cost reports are audited
- Charge compression leads to under-estimation of the cost of higher cost items and services
  - CCRs assume that all items within a department get the same markup, but expensive items typically have a lower percentage markup than inexpensive ones
- Circularity of using estimated costs to calculate the weights and then measuring their accuracy by comparison to the same estimated costs

19

How Can You Tell That Accuracy Has Improved?

- Typical MedPAC evaluation is tautological.
  - MedPAC evaluations show weights based on "cost" yield payment closer to "cost"
  - Does not provide an independent assessment of the accuracy of "cost"
- Is there any independent benchmark for accuracy of cost estimate?
- What about psychiatric PPS (IPF PPS) per-diem rates?
  - Psych discharges split 33%/66% IPPS facilities/psych facilities
  - Psych facilities paid under new per-diem IPF PPS (not IPPS)
  - Stand-alone psychiatric facilities give a clean measure of cost and profitability of this line of services
  - Psych should be "acid test" for accuracy: proposed IPPS '07 methods result in 41% payment increase.
  - So, how does psych payment compare, IPPS vs IPF PPS?

20

Approximate Payment per Day for Psychiatric Cases, IPPS vs. Psych PPS

	Discharges Now Paid Under		
	IPF-PPS (psych PPS)	IPPS (general PPS)	% Diff.
Number of Discharges, 2005, (MedPAR)	586,000	233,000	
Raw 2005 Payment per Day (MedPAR)	$ 635	$ 752	18%
Net out IPF-PPS short stay adjustment		0.908	
Net out IPF-PPS casemix adjustment		0.979	
Adjusted 2005 Payment per Day	$ 635	$ 668	5%
Increase Under 2007 Proposed Weights		41%	
Proposed Payment Per Day, 2007 Wgts.	$ 635	$ 943	48%
Memo: Check with theoretical IPF-PPS rate			
Memo: IPF-PPS 2005 base rate	$ 576		
Memo: IPF-PPS avg ECT pmt per dischg	$ 25		
Memo: Theoretical IPPS avg pmt per day excl.	$ 601		

21

What Changes Might Improve Cost Report Data and the Accuracy of Cost-Based Weights?

- Establish cost report rules and guidelines to bring more consistency and uniformity across hospitals
- Create separate cost center for high-cost implantable devices
- Use multiple per diem rates for room & board
- Adjust for charge compression
- Exclude pediatric cases in calculating CCRs
- Increase the number of cost report audits and the number of items audited

22

What concerns are raised by the substantial redistributions?

- Could patients needing care in complex DRGs experience access problems?
- How will the changes affect the financial viability of certain hospitals?
- How might hard-hit hospitals respond?
  - Reduce charity care?
  - Cut unprofitable services like burn and trauma care?
  - Change their service mix?
  - Close?
- Could the changes discourage use of technology-intensive procedures that lead to lower lengths of stay?

23

APR DRGs

- CMS proposes to implement a consolidated version of APR DRGs in FY 2008 or earlier
- Assignment is based on severity not complexity
  - Device use adds complexity but not severity
  - Therefore, device use may not affect DRG assignment
- How will severity-adjusted DRGs affect new technology thresholds and the ability for a new technology to qualify for an add-on payment?
- Could DRG specificity be improved in other ways?
  - Redesign selected DRGs to better reflect patient severity based on CMS analysis and outside input
  - Revise and refine the complication/co-morbidity list
- Should ICD-10 be implemented before moving to APR-DRGs?
- Greater incentive for up-coding: proposed rule indicates CMS likely will apply a prospective adjustment to the rates

24

Next Steps/Recommendations

- MedPAC examine technical issues in CMS methodology
- CMS withdrawal of HSRVcc weights this year
- Issuance of charge-based weights for FY 2007
- Recommendations to improve collection of actual cost data under PPS
- Cost-report based DRG reforms follow cost data reforms

25

Appendix

26

Consolidated Severity DRGs

- Impact of CS-DRG combines:
  - Severity adjustment (intended)
  - DRG vs APR-DRG mismatch (unintended?)
- DRG/APR-DRG mismatches
  - Some are easy to spot (e.g., no biliateral hip APR-DRG).
  - Some are more subtle (APR-DRG and DRG classify cases into different DRGs).
  - Mismatches not resolved on CMS file released with 2007 proposed rule.
- CS-DRG should be thoughtfully restructured to avoid unintended impacts of APR-DRG/DRG mismatch.

27

A Few Examples of CS-DRG and DRG Mismatch

Using 2004 MedPAR with CS-DRG as released with 2007 proposed rule:

- DRG 103, heart transplant: CS-DRG weight is one-third lower, does not classify some cases as transplant.
- DRG 471, bilateral leg joint: CS-DRG weight 19% lower; no separate bilateral joint APR-DRG.
- DRG 123, cardiac death: CS-DRG weight is one-quarter lower; splits cases across DRGs, only half at severity level 4
- DRG 496 chemotherapy with acute leukemia: CS-DRG weight 36% lower, does not recognize this high-cost subset of cases.

28

ATTACHMENT 3

Analysis Benchmarking Charge Mark-Ups Found in OPPS to External Data on Costs

1

Charge Compression for Implantable Devices:
Does it exist?

Preliminary results

May 9, 2006

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2

Charge compression definition

"Charge compression results from the interaction of hospitals' methods of setting charges and CMS's method of converting those charges to costs. Generally, CMS uses a single CCR (cost to charge ratio) to convert the charges for all services in a single revenue center, such as pharmacy, into costs. Within a revenue center, however, some hospitals mark up inexpensive products more than they do expensive products, which leads to charge compression." (MedPAC, 2005 report to Congress)

Our task was to examine if charge compression exists for implantable medical devices.

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3

We calculated that CMS estimates implantable medical devices at 79% of their actual acquisition cost.

- Hospital charge masters tend to reflect lower mark-ups for high-cost implantable medical devices.
- By using a departmental average cost-to-charge ratio to reduce charges to costs, CMS under estimates the costs of high-cost devices and over estimates the costs of low-cost devices.
- Because the costs for these devices are packaged into the cost of the procedure, under estimates of the costs of the devices leads to under estimates for the costs of procedures for implanting devices.

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Due to charge compression, CMS's biased cost estimates lead to under reimbursement for implantation of medical devices

- CMS uses the median cost estimate to calculate the relative weight for procedures and the APCs that the procedures group to.
- The bias in the cost estimates leads to under payments for some procedures and overpayments for others.
- CMS could consider using findings (from this or other research) to adjust for the measurable bias from charge compression.

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The Moran Company (TMC) was asked by Medtronic to:

- Assess the presence and magnitude of charge compression related to implantable medical devices.
- Build on previous published work on charge compression which focused on drugs.

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6

We used two sources of data for this study:

- For *charges*, 2002 hospital outpatient prospective payment system (OPPS) final rate setting file:
  - While separate pass-through payment for a few new devices continues, 2002 was the last year that many devices were paid separately under pass-through payments and as a result had separate C-codes to identify their specific charges.
- For *costs*, IMS Health's Hospital Supply Index (HSI) data covering 2002
  - Reports volume and price information for devices and supplies purchased by short-term acute care hospitals.

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Extensive manual matching of IMS cost data to the OPPS C-codes was required

- We manually matched each C-code from OPPS to device names in the IMS data.
  - This required research into device names and product descriptions.
- We limited the study to implantable medical devices. We excluded C-codes for the following:
  - Drugs
  - Radiopharmaceuticals
  - Single-use devices
  - Other supplies

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8

We examined how the "mark-up" changes when the cost of a device changes

- 100% would mean charges exactly equally the device cost
- Examples from our data:
  - C1788 – Port indwelling, (implantable). Average cost of $216, average charge of $1,039. Estimated mark-up of nearly 480%.
  - C1772 – Infusion pump, programmable (implantable). Average cost $9,242, average charge of $13,607. Estimated mark-up of 147%.

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9

A 10.0% increase in costs for implantable devices can be expected to lead to a 1.2% decrease in the charge multiple

- Results are statistically significant.

	Intercept		Ln(Cost)		
	Parameter	t-value	Parameter	t-value	Adj R-square
Ln(Charge multiple)	1.83815	<.0001	-0.12086	.0007	0.2168

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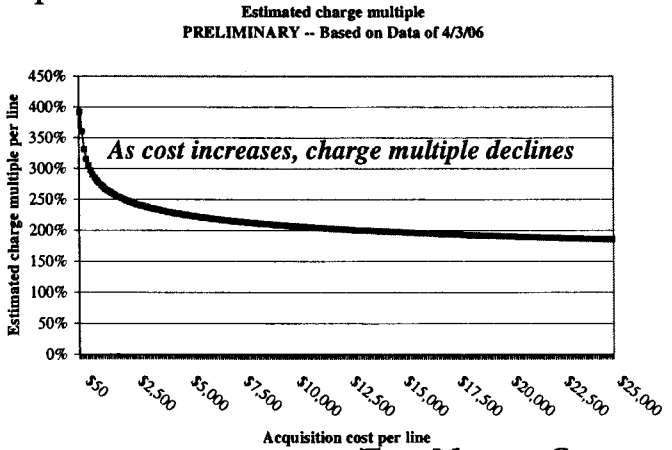
10

Graphically the relationship between charge multiple and cost looks like this



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11

Comparing our predicted acquisition cost to median unit CMS 'costs' from the OPPS claims

- OPPS had higher costs than predicted in 10 C-codes or 22% of the time, but
- OPPS had lower costs than predicted in 35 C-codes or 78% of the time.

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12

Overall CMS underestimates the cost of implantable devices by $88 million

- When weighting by units, the total difference in dollars when OPPS estimated costs were higher than predicted was: $2.5m
- But, when OPPS estimated costs were lower then predicted, the total difference in dollars was: $90m!!!!

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13

Using HSI data and our model: We estimate that OPPS only captures 79% of estimated costs

- Based on median cost from OPPS, we estimate total costs of $327m for implantable devices.
- Based on HSI data, we estimate the actual total costs to be $415m.

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14

Assuming that the goal is to reimburse hospitals for their costs for the devices, what adjustments can be made to improve the accuracy of the reimbursements in the future?

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ATTACHMENT 4

Analysis and Proposed Charge Compression Adjustment

Memorandum

To: IPPS 2007 Proposed Rule analysis clients
From: Christopher Hogan, Direct Research, LLC
Subject: A Proposed Solution for Charge Compression
Date: Revised 6/8/06 to show hospital coding quality.

Executive Summary

This memorandum presents an adjustment for charge compression for supplies and devices. The research does the following:

- Uses regression analysis to estimate the average amount by which cost-to-charge ratios (CCRs) vary across sub-categories of supplies and devices, for example, implantable devices versus general supplies;
- Applies these national average CCR adjustments to individual hospital's supplies CCRs, generating a "synthetic estimate" of CCRs for supplies sub-categories in every hospital. (This is done budget-neutral, keeping total estimated Medicare inpatient supplies cost in each hospital the same before and after adjustment);
- Calculates national average share of supplies charges by sub-category for each DRG, and applies these national charge shares to MedPAR records to produce estimated charges for supplies sub-categories on each MedPAR record. (This step could be skipped if 100% SAF data were used instead of MedPAR);
- Calculates "decompressed" cost by multiplying supplies sub-category CCR by supplies sub-category charges on each claim (along with the other components of costs);
- Generates DRG weights using these "decompressed" costs.

In effect, we take advantage of the detailed coding of supplies charges by revenue center on claims data, to split up the single cost-report CCR into separate CCRs for each supplies sub-category. That split is based on the strong statistical association between mix of supplies charges (by revenue center) in a hospital and the supplies CCR in a hospital. By pooling the information from all hospitals in a regression, we get one set of CCR adjustments reflecting national average CCRs for the sub-categories. We then apply that one national-average set of adjustments to every hospital (combining the adjustments with the hospital's actual supplies CCR), and from there put a "decompressed" estimate of cost on each MedPAR record.

The findings can be summarized as follows:

There is a strong and statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's average CCR for supplies. Hospitals with a higher share of charges in the pacemaker and implantable device revenue centers (0275, 0278) have higher supplies CCRs.

The coefficients from this regression provide a data-driven adjustment for creating CCRs for sub-categories of supplies. Only four of the supplies sub-categories have enough charges, on average, to allow such a statistical estimate. On net, after all budget-

neutrality adjustments, the average CCRs for the supplies sub-categories are shown in Table ES-1. The average CCR for all supplies together was 0.33 (top line). But the regression analysis suggests substantial variation in CCR by category. The pacemaker category (which also includes hospital charges for most defibrillators) has an estimated CCR of 0.46 (or just over a 100% average markup). General supplies, by contrast, has an estimated CCR of 0.24 (or just over a 300% average markup).

Table ES-1: Estimated CCRs for Supplies Sub-Categories

Supplies subcategory	Net average CCR after budget-neutrality adjustment
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29

Source: Analysis of 2004 5% standard analytic file and 2003 hospital cost report data

This has a significant impact on some DRG weights. Mainly, cost-based DRG weights would increase for DRGs with substantial charges in the implantable devices and pacemaker/defibrillator revenue centers. These are almost entirely cardiac and orthopedic surgery DRGs. In particular, for defibrillators, the old charge-based weights really may have amounted to "rough justice", in the sense that a properly calculated cost weight (with separate CCRs for device subcategories) would not be that different from a charge-based weight.

A spreadsheet accompanying this memo gives weights for all DRGs.

Here are a few additional comments on the method.

First, this approach seems to meet several tests of the internal validity of the method and external validity of the numbers. The section of the memo regarding the regression gives several statistical "robustness checks" on the numbers. In almost every case, the regression generates the same differential between CCR for implantables and CCR for general supplies. In other words, I would have gotten the same numbers in Table ES-1 from any of several variations on the basic regression. In addition, the "face validity" of the approach is good because the revenue center categories of interest in fact account for a large share of hospital supplies charges. In other words, they are big enough that we *ought* to be able to see their impact on the overall supplies CCR. Finally, although not discussed in the memo, the order-of-magnitude of the resulting CCRs and costs looks roughly correct when compared to the recent Moran et al. study using IMS data on cost of implantables.

Second, some supplies categories are just too small to be used in a regression analysis of this sort. In particular, intraocular lenses account for just 1% of total hospital supply charges (combining inpatient and outpatient). I cannot use this approach to generate a separate CCR for IOLs.

Third, I have done a full "micro-simulation" here, putting detailed costs on each MedPAR record. Much of the complexity of this approach comes from having to put those costs on each and every claim. But, at root, this is a set of national average adjustment factors, applied across-the-board. I expect that a simple national-average adjustment to US charge and cost totals would yield essentially the same answers as are shown here, though I have not demonstrated that. If so, much of the complexity of the method could be avoided -- you could do it in a spreadsheet, once you have the regression results.

Fourth, there is no barrier to refining this further (e.g., separating implantables charges for cardiac and orthopedic by DRG), except the limits of regression analysis. Sub-sub-categories cannot be too small or too correlated with one another. Also, there would appear to be no obvious barrier to doing this for other sub-categories of cost if desired. In other words, again subject to the limits of regression analysis, this could be a tool for CMS to address finer distinctions in CCRs in areas other than supplies.

1 BACKGROUND AND OVERVIEW

For purposes of this analysis, *charge compression* refers to hospitals' practice of taking lower average markups on high-cost devices and supplies, relative to the markup for more routine supplies.

Charge compression is a policy concern because CMS' cost calculations do not account for this. To estimate cost, CMS applies one cost-to-charge ratio (CCR) to all supply/device charges in a hospital. Ultimately, that practice stems from cost reports that pool all supply/device costs within the hospital on a single data reporting line. With charge compression, the use of one pooled CCR for all supplies and devices understates the cost of high-cost devices and overstates the cost of routine supplies.

Fixing charge compression requires that we establish different CCRs for different categories of supplies and devices. The question is how to go about that in a way that CMS might accept, using only CMS administrative data.

Obviously, we cannot estimate each individual hospital's exact CCRs for supply/device sub-categories using CMS administrative data. That hospital-specific information is lost when all supplies/devices costs are mixed together on the cost report.

Instead, we propose a single national-average set of adjustments to hospital CCRs, based on two observations.

- First, revenue center codes on hospital claims provide a detailed breakout of supply/device charges. For example, charges for implantable devices (a category for which charge compression is a concern) are reported separately from general supplies. Further, hospitals by-and-large appear to use these categories correctly. For example, roughly 90 percent of defibrillator discharges have a large charge in either the implantables or pacemaker revenue center.
- Second, there is a strong and stable statistical association between a hospital's mix of supply/device charges by revenue center and the hospital's average CCR for all supplies and devices. All other things equal, the larger the fraction in implantable devices, the higher the CCR, while the larger the fraction in general supplies, the lower the CCR.

So, in broad outline, what we propose to do here is to pool information across hospitals to establish how CCRs vary across sub-categories of devices and supplies, on a national average basis. We pool that information in a regression, looking at the impact that the mix of charges by sub-category has on the overall hospital supplies CCR. The regression coefficients tells us which CCRs for the supplies sub-categories would give us the best fit to the hospital-level data on charge mix and supplies CCR.

We then combine the national average information on how CCRs vary across supplies sub-categories with each hospital's actual supplies CCR. In effect, we show what the hospital's CCRs for the sub-categories would have been, if it matched the national average in terms of higher and lower markups by supplies sub-category.

In generating these supplies sub-category CCRs, I was careful to maintain budget neutrality in each hospital by first "standardizing" each hospital's CCR. That process is described in the methods section. The upshot is that total supply/device costs in each hospital, after my creation of the sub-category CCRs, exactly match total supply/device costs before I made any adjustments.

Following the language used by the U.S. Bureau of the Census, these are "synthetic estimates". We have synthesized the detailed (sub-category) CCR data for each hospital in a way that

- keeps the hospital aggregate data unchanged (total supply/device costs match the existing hospital total), and
- uses national average patterns of CCRs to model the detailed sub-category CCRs within each hospital.

2 METHODS

2.1 Regression specification and sensitivity analysis.

To estimate separate CCRs by revenue center category, I did the following:

- Take the 5% LSD SAF inpatient and outpatient files, CY 2004.
- Pass the inpatient file through the grouper and append the V23 (2006) DRG. (This is required to be able to model the 2007 Proposed Rule rates, and because we will match summary information from this file to 2005 MedPAR).
- Identify all revenue center codes that CMS counts in the supplies and devices revenue center group.
- Aggregate the revenue center codes that individually accounted for less than 5% of supplies charges. (It seemed unlikely that a hospital-level regression would give a stable estimate of impact for rarely-used charge categories.)
- Match to 2003 cost reports with charge-trimmed CCRs:
  - Toss extreme outliers using CMS criteria (<.01, >10) for supplies CCR
  - Toss the top and bottom 2.5% of hospitals, in terms of supplies CCRs, charge-weighted. (That is, drop the hospitals accounting for 2.5% of charges at the top and bottom of the supplies CCR distribution).
- To control for the hospital's overall charging policy, calculate the average CCR for all ancillaries *other than* supplies, based on the cost report data. (An alternative specification used hospital total CCR for all items other than supplies. In either case, we must exclude supplies from the control variable.)
- Run this regression, hospital-level, weighted by supplies charges:
  - Hospital supplies CCR =
    constant +
    hospital CCR for ancillaries excluding supplies +
    percent of supplies by revenue center.
- A larger coefficient on a supplies revenue center shows that supplies in that revenue center are associated with higher average CCR. The model then predicts the differential CCRs across the supplies centers (ie, evaluate the model for a value of 1.0 in one supplies center and 0 in the others.)
- Run several variations, including both inpatient-only and inpatient-plus-outpatient supplies. In theory, because the cost report pools all costs, the inpatient-plus-outpatient model is the preferred specification.

2.1.1 Results

Table 1 profiles 2004 inpatient and outpatient supplies charges for roughly 3,000 short-term general PPS hospitals for which cost report data were available, and for which the supplies CCR on the cost report was kept after trimming. (In other words, the hospitals that will be used to calibrate the DRG weights.) Only four supplies revenue-center categories individually account for at least 5 percent of total supplies charges. These four will be entered separately into the regression. The remainder will be combined into a single "all other" category.

Table 1: Profile of Medicare Hospital Supplies Charges, Calendar Year 2004, 5% Sample Files

Rev Ctr Code	Short Label	In-patient ($B)	% of inpat	Out-patient ($B)	% of outpat	Total ($B)	% of tot	Memo: Inpat share	Memo: Outpat share
	Supplies Total	$ 2.19	100%	$ 0.45	100%	$2.63	100%	83%	17%
0270	General classification	$ 0.71	32%	$ 0.12	27%	$0.83	31%	85%	15%
0278	Other implants	$ 0.68	31%	$ 0.10	22%	$0.79	30%	87%	13%
0272	Sterile supply	$ 0.44	20%	$ 0.13	29%	$0.57	22%	77%	23%
0275	pace maker	$ 0.21	10%	$ 0.05	12%	$0.27	10%	80%	20%
0271	Nonsterile supply	$ 0.07	3%	$ 0.01	2%	$0.08	3%	90%	10%
0279	Other devices	$ 0.03	1%	$ 0.01	2%	$0.04	1%	82%	18%
0274	Prosthetic/orthotic dev	$ 0.02	1%	$ 0.00	0%	$0.02	1%	94%	6%
0276	Intraocular lens	$ 0.00	0%	$ 0.02	4%	$0.02	1%	1%	99%
0622	Incident to other dxc svc	$ 0.01	0%	$ 0.00	1%	$0.01	1%	76%	24%
0621	Incident to radiology	$ 0.01	0%	$ 0.01	1%	$0.01	1%	51%	49%
0624	Medical investig dev	$ 0.00	0%	$ 0.00	0%	$0.00	0%	97%	3%
0273	take home supplies	$ 0.00	0%	$ 0.00	0%	$0.00	0%	52%	48%

Source: Analysis of 5% sample inpatient and outpatient SAF, for short-term general hospitals with 2003 cost report and non-trimmed CCR (roughly 3,000 hospitals).

Note: Data totals reflect 5% sample data. If estimated US totals are desired, multiply by 20.

The table raises an issue with the treatment of intraocular lenses (IOLs). As the rightmost columns of Table 1 show, IOLs are almost exclusively used in outpatient surgery. They account for only about 1 percent of total hospital supplies charges. We believe this is too small a category to allow to estimate a separate CCR for IOLs. They simply do not account for a large enough share of total hospital supplies costs.

A second factor that is worth noting (but cannot be seen on the Table 1 summary) is that the "pacemaker" category actually appears to capture both pacemakers and implantable defibrillators (ICDs). To show this, and to characterize the level of coding accuracy in general, we flagged claims in the 5% sample file that had at least $5,000 or at least $10,000 in charges in implantable devices (revenue center 0278) or in the pacemaker category (revenue center 0275). In other words, for selected DRGs, we wanted to check the extent to which hospitals in fact reported a large charge in the supplies revenue centers of particular interest for this analysis.

Table 2 shows the results for the top 20 DRGs in terms of fraction of cases with significant implantable device charges, using 2004 5 percent sample inpatient SAF data. Coding appears reasonably good but not perfect.

- For defibrillators, roughly 90 percent of defibrillator cases had at least $10,000 in charges in either the pacemaker or implantable device charge category. About half the time, the charge appears in the pacemaker revenue center.
- For spinal fusions of various types, between two-thirds and three-quarters of cases would meet that $10,000 threshold. More complex spinal fusions (e.g., combined anterior/posterior) are more likely to meet that charge threshold.
- For pacemakers, if we switch to a $5,000 threshold, between 80 and 90 percent of cases meet the threshold.
- For hip replacements, a bilateral hip is almost exactly twice as likely to meet the $10,000 threshold as a unilateral hip.
- For stents, less than 40% meet the $10,000 threshold, but about three-quarters meet a $5,000 threshold.

Table 2: Top 20 DRGs by Percent of Cases With Significant Implant Charges

			At least $10K charges in:			At least $5K charges in:		
2006 DRG	Brief Title	Discharges (5% SAF)	Implantable (0278)	Pacemaker (0275)	Either 0275 or 0278	Implantable (0278)	Pacemaker (0275)	Either 0275 or 0278
535	Defib	363	49%	55%	91%	53%	58%	92%
515	Defib	2287	42%	59%	91%	45%	62%	92%
536	Defib	423	49%	52%	89%	55%	54%	90%
496	Spinal fusion	171	83%	0%	83%	86%	0%	86%
546	Spinal fusion	119	73%	0%	73%	78%	0%	78%
552	Pacemaker	4334	6%	67%	72%	11%	83%	89%
551	Pacemaker	2806	11%	62%	71%	17%	77%	87%
471	Hip/Knee bilateral	873	71%	0%	71%	78%	0%	78%
497	Spinal fusion	1416	64%	0%	64%	72%	0%	72%
498	Spinal fusion	1026	62%	0%	62%	71%	0%	71%
118	Pacemaker	372	3%	51%	55%	5%	78%	83%
104	Heart valve	1066	43%	8%	47%	68%	9%	71%
105	Heart valve	1574	42%	6%	44%	66%	7%	68%
545	Hip/knee revision	2219	42%	0%	42%	58%	0%	58%
519	Spinal fusion	647	41%	1%	41%	64%	1%	64%
557	PTCA with stent	5421	38%	0%	38%	75%	0%	75%
525	Heart assist dev	8	38%	0%	38%	38%	0%	38%
111	Major heart proc	544	36%	0%	36%	41%	1%	42%
558	PTCA with stent	8669	36%	0%	36%	74%	0%	74%
544	Hip/knee	21722	35%	0%	35%	63%	0%	64%

Source: Analysis of 2005 5% LDS SAF inpatient file

We calculated the fraction of total supplies charges for the top four revenue center categories, for each hospital. We did this separately for inpatient and outpatient claims.

These charge shares became explanatory variables in the regression below. The omitted category is "all other supplies centers", consisting of everything on Table 1 except the top four categories.

The regression was run with a preferred specification and numerous alternatives. The purpose of the alternatives is to demonstrate that the results are robust to modest variations in the methodology. The specifications are given below.

1) Preferred specification: use total (inpatient and outpatient) charges for calculating charge shares, use all-ancillary CCR excluding supplies as control variable.
2) Exclude most influential top and bottom 1% of hospitals using the DFFITs statistic (explained below).
3) Excluding most influential top and bottom 5% of hospitals using the DFFITS statistics.
4) Use inpatient charges only, for calculating the supply sub-category charge shares.
5) Use total hospital CCR (excluding supplies) instead of CCR for ancillaries excluding supplies.

The DFFITS statistic may require additional explanation. The DFFITS statistic provides a measure of how "influential" a particular datapoint is in determining the slope of the regression line. An influential datapoint is one that strongly affects the slope of the line (due, for example, to being an outlier, or to having an extreme value for one of the predicting variables). By eliminating the most influential datapoints and rerunning the regression, we demonstrate that the regression coefficients are not being driven by a few influential datapoints (e.g., a few large or outlier hospitals), but instead reflect the average relationship of the bulk of the datapoints in the analysis.

The coefficients on mix of supplies charges show a remarkable stability across the regression specifications (Table 3). In each case, the coefficients on implantables and pacemakers are positive and statistically significant, while the coefficients on the other categories are weakly negative.

The final column on the table is the best way to demonstrate the stability of the estimates. The coefficients on the individual categories may vary slightly across specifications. But the differential between the two largest categories -- general supplies and implantables -- hardly changes at all across the specifications. Because we propose to implement a CCR adjustment in a budget-neutral manner, the differential between general and implantable supplies is a good guide to how large the net impact of the CCR adjustment will be. For all except the last specification, the regressions say that we would create a net 18 percentage point differential between the adjusted CCR for implantables (revenue center 0278) and the adjusted CCR for routine supplies. For the pacemaker/defibrillator category (0275), the differential is slightly more variable, ranging from 0.18 to 0.24 across the specifications. The bottom line is that any of the variations shown would generate roughly the same impact on CCRs after budget-neutrality adjustment, because all of them show roughly the same differentials among the categories.

Table 3: Predicting Hospital-Level Supplies CCR Based on Mix of Supplies Charges.						
	Variable	Coeff	Std Error	T-value	P-value	Implantable less General Supply Coeff
1: Preferred Specification, Use Inpatient Plus Outpatient Supplies Charges						
	Adj R-Sq 0.1928					
	Intercept	0.108	0.027	3.91	<.0001	
	CCR, ancill. Excl supplies	0.717	0.031	23.07	<.0001	
	pct_0270 (general supplies)	-0.049	0.027	-1.81	0.0711	
	pct_0278 (implantables)	0.133	0.029	4.56	<.0001	0.18
	pct_0272 (sterile supplies)	-0.025	0.032	-0.78	0.4376	
	pct_0275 (pacemaker)	0.160	0.040	4.02	<.0001	0.21
2: Same as 1, but toss out top and bottom 1% of influential datapoints						
	Adj R-Sq 0.2039					
	Intercept	0.103	0.027	3.88	0.0001	
	CCR, ancill. Excl supplies	0.717	0.030	23.62	<.0001	
	pct_0270 (general supplies)	-0.040	0.026	-1.52	0.1285	
	pct_0278 (implantables)	0.138	0.028	4.90	<.0001	0.18
	pct_0272 (sterile supplies)	-0.039	0.031	-1.26	0.2075	
	pct_0275 (pacemaker)	0.178	0.039	4.60	<.0001	0.22
3: Same as 1, but toss out top and bottom 5% of influential datapoints						
	Adj R-Sq 0.2269					
	Intercept	0.100	0.026	3.88	0.0001	
	CCR, ancill. Excl supplies	0.709	0.028	25.20	<.0001	
	pct_0270 (general supplies)	-0.037	0.025	-1.48	0.1396	
	pct_0278 (implantables)	0.142	0.027	5.33	<.0001	0.18
	pct_0272 (sterile supplies)	-0.024	0.030	-0.82	0.4128	
	pct_0275 (pacemaker)	0.143	0.037	3.86	0.0001	0.18
4: Use Inpatient Charges Only						
	Adj R-Sq 0.1924					
	Intercept	0.110	0.026	4.16	<.0001	
	CCR, ancill. Excl supplies	0.715	0.031	23.01	<.0001	
	pct_0270 (general supplies)	-0.049	0.026	-1.92	0.0547	
	pct_0278 (implantables)	0.128	0.028	4.66	<.0001	0.18
	pct_0272 (sterile supplies)	-0.020	0.031	-0.63	0.5271	
	pct_0275 (pacemaker)	0.132	0.040	3.32	0.0009	0.18
5: Same as 1, but use total hospital CCR excluding supplies as control variable						
	Adj R-Sq 0.2079					
	Intercept	0.123	0.027	4.61	<.0001	
	CCR, total excl supplies	0.611	0.025	24.48	<.0001	
	pct_0270 (general supplies)	-0.098	0.026	-3.70	0.0002	
	pct_0278 (implantables)	0.105	0.029	3.64	0.0003	0.20
	pct_0272 (sterile supplies)	-0.085	0.031	-2.71	0.0068	
	pct_0275 (pacemaker)	0.141	0.039	3.58	0.0004	0.24
Source: Analysis of 5% SAF 2004 inpatient and outpatient files matched to 2003 hospital cost reports.						
Notes: Dependent variable mean is 0.33 for all regressions. Number of observations is roughly 3,000 for all regressions. Regressions were weighted by supplies charges.						

2.2 Practical details of implementation and a choice of methodology.

The previous section provided evidence that the CCRs for implantables and pacemakers/defibrillators are substantially higher than the CCRs for other supplies. This section describes describes what we believe is the preferred method for implementing the adjustment, then briefly describes alternative approaches that might have been used.

2.2.2 Description of preferred methodology

To implement the adjustment, we chose to split up the supplies data on each record into five sub-categories (top four revenue centers plus all other). We did this using a U.S. Census-style "synthetic estimate" approach. That is, we will start with the actual hospital data on hospital charges and CCRs for supplies. Then, beneath the total supplies figure, we generate "synthetic" estimates of the five separate charge sub-categories we wish to estimate. That split is done by imposing the national average charge shares by DRG (from the SAF) to estimate charges in the sub-categories, and imposing the estimated national differentials in CCRs (from the regression above) to estimated CCRs in the sub-categories. (Note that the only reason we use the SAF charge shares here is that we wanted to work from MedPAR, where supplies charges are rolled up to a single total. If we had 100% SAF file data, we could simply have read the exact charges shares from every claim, rather than impute them based on national average supplies sub-category charge shares by DRG.). A separate budget-neutrality (standardization) step ensures that this will leave each hospital's total supplies charges and costs (across all DRGs) unchanged.

These "synthetic" estimates for the five categories can then be used in place of the single supplies charge and cost on the original record. We can then proceed with any of the DRG weight approaches, treating those five new supplies sub-categories however we would have treated the original supplies category.

Before proceeding, it is worth saying that this is probably the most complex and precise method that could be undertaken. It is possible (even likely) that an approximate aggregate adjustment to the data would yield the nearly the same results with far less effort. But the main advantage of this approach is that, once we have done it, we can apply any of the DRG weight calibration methods to the resulting "decompressed" claims data.

The method works as follows.

- **Split the MedPAR supplies charges on each claim into the five sub-categories.** Use 2004 inpatient SAF 5% data to calculate, for each DRG, the percent of supplies charges in each of the five sub-categories. (Recall that the 2006 DRG had previously been appended to this file.) Merge this to MedPAR by DRG, multiply the actual MedPAR supplies total on each line by the DRG sub-category charge shares. This is

our is our synthetic estimate of supplies sub-category charges for each MedPAR record. If we had had 100% SAF data, we would either have skipped this step, or would have calculated the charge shares in greater detail (by DRG *and hospital*) before applying them to MedPAR.[1]

- **Use the coefficients from the preferred regression specification as additive factors for adjusting each hospital's supplies CCR**. Before any standardization or budget-neutrality adjustment, we would assume that the hospital's CCR for general supplies would be .049 below the CCR for the "all other supplies" category (the omitted category in the regression), and that the CCR for implantables would be .133 percent higher, and so on (Table 3, preferred regression specification).
  - **First, we must "standardize" the actual hospital supply CCR to account for the existing mix of supplies used in that hospital**. For example, a hospital with a high share of implantable devices would have a high CCR. We need to remove the effect of the charge mix first, then apply the regression coefficients to that "standardized" supplies CCR. To do this, we sum the estimated supplies charges by sub-category by hospital using MedPAR with the supplies sub-category charges appended. This tells us what fraction of total supplies charges is in each category in each hospital. Multiply by the regression-based adjustment factors to find how much we expect that charge mix to have raised or lowered the hospital's supplies CCR. Then subtract that amount from the hospital's actual supplies CCR. The resulting standardized CCR is the CCR we would expect at each hospital, if each hospital had had exactly the same case mix. ***This net effect of this is to impose budget-neutrality separately on each hospital. Total supplies costs, after decompression adjustment, equal total supplies costs prior to adjustment, separately for each hospital.*** That's because before we apply the adjustment, we have backed out the average impact of that adjustment in this standardization step.[2]
  - **Then, the hospital CCR for each of the five supplies categories is the standardized CCR for all supplies, plus the five additive factors from the regression.** So, for example, the CCR for general supplies is the standardized hospital supply CCR less .049. The CCR for implantables is the standardized hospital supply CCR plus .133. And so on. The CCR for the "all other" supplies category is the standardized hospital CCR (plus zero).

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[1] If 100% SAF data were used this step would not be necessary. Alternatively, if 100% SAF data were available but CMS wished to use MedPAR for the rate setting, we could have calculated the SAF-based charge shares by DRG *and hospital*, and therefore captured each hospital's unique charge shares instead of imposing a national average. CMS has stated that it does not want to use the SAF directly for setting the hospital rates each year. Under this approach, the general pattern of charges from a recent SAF would be imposed on the MedPAR. This avoids having to use current-year SAF data as part of the ratesetting process, at the cost of either imposing national average charge shares by DRG (as is done here), or by imposing the hospital's average charge shares by DRG on all records for that hospital and DRG. In either case, the SAF summary would be a separate step, and the results of that summary would be merged to MedPAR in order to get estimated charges in the supplies sub-categories.

[2] The standardization adjustments were small, on average. On a charge-weighted basis, 1st and 99th percentiles of the standardization adjustments were -0.053 and 0.048, and the range from 25th to 75th percentile was -.007 to -.019. These should be compared to an average supplies CCR of 0.33.

    - Multiply charges by CCR to get estimated cost for each of the five supplies sub-catgories, on each claim.
- **Check budget-neutrality for supplies costs.** That is, total US supplies costs using a single CCR for supplies in each hospital must equal total supplies using the synthetic estimate of the five separate supplies categories. In fact, total supplies cost pre- and post-decompression were equal, as they should be by construction.
- **Add the budget-neutral supplies sub-category CCRs to the cost report file**. Read the final, budget-neutral supplies sub-category CCRs off the claims file, by hospital, and add them to the cost report file.

The end result is an enhanced MedPAR file with "synthetic estimates" of charges and costs in the five supplies sub-categories, and an enhanced cost report file with five estimated CCRs for supplies categories instead of one such CCR. The synthetic estimates impose national average charge shares by DRG on each MedPAR record, and impose the national average CCR differentials across the five supplies sub-categories onto all hospitals. (Again, if 100% SAF data were available, we would have either used the actual charge shares or have imposed average charge shares by DRG and hospital rather than by DRG.) The actual hospital data reflect a combination of its own actual supplies charges and CCR and these splits imposed using national average data.

2.2.1 Brief discussion of preferred methodology and alternatives.

This is presented as a plausible way to implement these changes, but is certainly not the only way it could be done. For example, if the entire analysis were done from the SAF instead of MedPAR, we could use actual charge shares throughout and would not need to impose national average charge shares by DRG onto the MedPAR data. This section focuses on the current approach and discusses things that might have been done differently. The end of the paper suggests enhancements or outright alternatives to this approach.

First, with an additive factor used to create the sub-category CCRs, there is the potential for the sub-category CCRs to turn out negative. Sooner or later, that's bound to happen. I checked that, and in this analysis 0.05% (decimal 0.0005) of supplies charges were negative. Obviously this could be fixed by imposing some nominal floor on the CCR (e.g., 0.01) and would have no tangible impact on the results.

Second, the entire process was set up to be additive: the regression gives additive factors for adjusting the CCRs, these are in fact added to the hospital's supplies CCR to generate the sub-category CCRs, and the standardization (budget-neutrality adjustment) was done by subtracting out the hospital-average effects of the CCR adjustments from the hospital's supplies CCR. This approach is internally consistent, and in addition simplifies the standardization by allowing you to ignore the mean value of the other (additive) factors in the regression.[3] This seemed by far the simplest approach.

[3] On a national average basis, the CCR adjustments average to 0.034. That is, by themselves, straight from the regression, they are not budget-neutral. That's because the other factors in the regression (the constant times its coefficient and the control variable times its coefficient) do not average to zero. But there was no

In theory, it should be possible to set up a multiplicative model instead, one in which the predicted CCR for the sub-categories is based on the ratios to the hospitals average supplies CCR (instead of factors added to the hospital's supplies CCR).

A typical approach to generating a multiplicative model is to run a log-log or log-linear model (predict the log of the supplies CCR rather than the CCR itself), then transform the resulting regression estimates into a multiplicative formula at the end by taking anti-logs. (If log(CCR) = A + B, thenCCR = antilog(A)*antilog(B)). A log-log model is not feasible because the supplies sub-category charge shares could be zero. Even a log-linear model (predict log of supplies CCR based on charge shares) may be questionable, as CCRs can be very small and the log transformation is highly nonlinear close to zero.

I ran one log-linear model just to investigate the potential for a multiplicative approach to this adjustment. I regressed log of supplies CCR on the control variable (ancillary CCR excluding supplies) and supplies charge shares, as above, weighting by supplies charges. I then transformed the results into a multiplicative formula and calculated the predicted sub-category CCRs (at the national average value of the control variable). The results where quite close to the additive model: the raw CCR for implantables was 0.19 higher than the raw CCR for general supplies, and the raw CCR for pacemaker/defibrillator was 0.21 higher. These are virtually identical to the differentials show in Table 3, right hand column (the additive model). I therefore concluded that a multiplicative model would give roughly the same results as an additive model.

Fourth, I have made this budget-neutral for inpatient supplies charges, as the proposal here is to apply it to inpatient claims. If this adjustment were applied simultaneously in the IPPS and OPPS settings, you could either make it budget-neutral separately within each system, or make total inpatient and OPD supplies costs budget-neutral. Clearly, there would be operational advantages to keeping the IPPS and OPPS adjustments separate, at the cost of having slightly different net budget-neutral supplies sub-category CCRs applied in the two systems. You can see from Table 1 above that the mix of supplies is modestly different in inpatient and outpatient settings. Thus, a budget-neutrality adjustment in the OPPS setting would probably lead to slightly different net CCRs for the sub-categories than was obtained in the inpatient setting.

2.3 Apply This Adjustment to DRG Weights Calculated Four Ways.

After having put the detailed cost data on every claim, I need to outline how the "decompressed" costs were used in the CMS HSRVcc method. For other approaches to cost-based weights, the modification is obvious -- use the decompressed supplies cost, not the original (compressed) supplies cost.

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need to force this to be budget-neutral at the national level first, before forcing budget-neutrality in each hospital. That additive factor of 0.034 simply got tacked onto each hospital's standardization factor. So, one can simply ignore the other factors in the additive model. If a multiplicative model had been used, it probably would have been necessary to pay more attention to the net impact of the other factors in the model.

To make HSRVcc work with this approach, I did the following:

- Rewrote the HSRV computer program to include the five supplies sub-categories instead of the one aggregate supplies category. So, HSRV would generate 14 charge-based weight for each DRG, one for each of the (now) 14 charge categories.
- Took the final, budget-neutral CCRs for these five categories in each hospital, trimmed them and took the hospital-weighted geometric mean CCRs. (This was in fact the purpose of drawing those CCRs off the claims file and putting them back onto the cost report file.)
- Multiplied these CMS-style (unweighted) CCRs by charges in the five supplies sub-categories to get the (unweighted) cost shares in those categories.
- Forced the total of those five cost shares to match the published CMS cost share for supplies in the aggregate. (So, on net, total estimated supplies cost share, adding the five sub-categories, was forced to match the published CMS value.)
- Weighted the (now) 14 charge-category DRG weights by the CMS-like cost shares to arrive at the final HSRVcc DRG weight.
- For the HSRVcc with corrected CCRs, I performed the same steps, but calculated correctly (charge-weighted) trimmed and weighted CCRs.

For the OPPS-style cost weights, I simply added up the costs on each claim (using the five supplies sub-categories instead of the aggregate supplies category), then proceeded with either traditional standardization or HSRV standardization.

The resulting weights are include in a spreadsheet accompanying this memo. The table below gives the gist of the results: Decompressing costs gives higher DRG weights for procedures using high-cost implantable devices.

Table 4: DRGs With 10K+ Discharges, Ten Largest Weight Increases from Decompression

				HSRVcc, incorrect (CMS) cost share			HSRVcc, correct cost share		
DRG	Short title	PPS Disch. 2005	2006 wgt	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
515	Defibrillator	57,279	5.52	4.15	4.69	13%	4.90	5.69	16%
552	Pacemaker	80,797	2.10	1.77	1.94	10%	1.97	2.23	13%
551	Pacemaker	53,077	3.10	2.63	2.82	7%	2.87	3.15	10%
498	Spinal fusion	21,188	2.78	2.53	2.64	4%	2.81	3.01	7%
497	Spinal fusion	30,517	3.62	3.33	3.48	5%	3.66	3.90	7%
520	Spinal fusion	16,310	1.68	1.47	1.52	3%	1.63	1.72	5%
471	Hip/Knee	15,407	3.14	2.74	2.91	6%	3.11	3.27	5%
491	Shldr/Elbow	22,356	1.68	1.60	1.64	2%	1.74	1.82	4%
545	Hip/Knee	43,873	2.48	2.41	2.48	3%	2.60	2.71	4%
558	PTCA w DES	189,047	2.21	1.43	1.49	4%	1.75	1.84	5%

3 POSSIBLE ADDITIONAL RESEARCH TOPICS.

This section briefly describes additional possible topics for research in this area.

3.1 Further refinements by MDC and revenue center.

There is no technical barrier to separating out charges by revenue center and DRG or MDC. So, for example, subject to the limits of regression analysis, we could try to estimate separate CCRs for cardiac versus orthopedic implantables, or for subsets of cardiac implantables.

In addition, the same technique might be applicable to other revenue centers, but that would depend strongly on the facts in each case. The clear limitations are those of regression analysis: the revenue centers would have to account for a reasonably large fraction of charges in the relevant category, and there could not be too much correlation among the shares of charges in the sub-categories.

3.2 Non-linear regression specification and modeling.

The current approach assumes a simple additive factor to the CCRs. (A fixed number of percentage points, if you will.) That was simple to do, and perhaps a reasonable choice, but it might not be the most natural model for how CCRs would be expected to vary. As described above, I estimated one non-linear model (log CCR as a function of supplies charge mix), and found much the same basic results as I did with the additive model. Nevertheless, for completeness, it might be reasonable to run the complete analysis all the way to DRG weights, using a multiplicative model.

3.3 Correct coding edits .

Table 2 demonstrated that hospital inpatient coding appeared reasonable but not perfect. For example, about 90 percent of defibrillator discharges had a large charge in either the pacemaker or implantable revenue centers. The question that might be addressed here is what (if anything) you would want to do about the other 10 percent of cases?

In the OPPS, a "correct coding" screen was applied to single-procedure claims prior to estimation of the APC weights, for the device-intensive APCs. Claims not passing the screen were not used to set the APC weight. More recently, CMS began requiring hospitals to report the device C-code on such claims to ensure that the charges were being properly captured.

While the concept is simple, the implementation in the inpatient setting might not be. First, the detailed charge data is only available on the SAF. A "correct coding" screen that required charges in the implantables revenue centers could not be directly applied to MedPAR.

Second, some DRGs involve a mix of cases with different levels of implantable device costs. For example, I believe that the "total hip replacement" DRG includes hips, knees, ankles and some other major joint procedures. There would not necessarily be any one "right" level of implantables charges to expect for those DRGs. Other DRGs, such as defibrillator and pacemaker implant, would appear to be more homogeneous. It would not seem unreasonable to screen out claims with trivial (e.g., less than $100) charges in the implantable or defibrillator category before calculating DRG weights.

One further possibility arises if the missing charges for the implantable devices are typically coded as general or routine supplies (that is, are captured in the MedPAR supplies charge category). If hospitals typically report the charges as supplies (and do not, for example, bundle them in with the operating room costs), then the correct-coding screen could be applied without eliminating any MedPAR claims records. It would work in two phases. First, a correct-coding screen would be applied to the SAF, to calculate the share of supplies charges by supplies sub-category for each DRG (or at the hospital by DRG level, using national average data to gap-fill the shares for those hospitals with no or few correctly coded claims). Then, these "correctly coded" charge shares would be applied to MedPAR to get the estimated charges by revenue center category. As long as the charge category on MedPAR captures the charge for the device, this approach would correctly allocate the charges to the implantables revenue centers. (If, by contrast, hospitals just bundle the implantables charge somewhere else, then this wouldn't work.)

3.4 Should this adjustment be budget-neutral?

Cost reports pool all costs for all sites and all payers. In particular, supplies costs reflect both Medicare and non-Medicare cases. If implantable devices account for a larger share of Medicare case-mix than they do of non-Medicare case mix, then in fact this adjustment should not be budget-neutral in total supplies costs. (Obviously, CMS will ensure that the entire weight estimation process is budget-neutral -- the issue here is supplies' share of total estimated costs). If the Medicare case mix is more highly weighted toward implantables, then the aggregate CCR on the cost report currently understates total Medicare supplies cost (because it reflect average supplies mix, not Medicare supplies mix).

This could be checked by using the HCUP all-payer discharge database, combining with the Medicare supplies sub-category charge shares by DRG, and determining whether or not the non-Medicare supplies mix has a lower weight on the pacemaker and implantables categories. It seems implausible that this would have anything more than a slight impact on the DRG weights.

3.5 Could this be done as an aggregate (DRG summary level) adjustment?

Finally, I suspect that the level of detail used in this analysis may be overkill. We are applying national charge shares and a national CCR differentials to the data to generate "decompressed" costs on each claim. Could we get nearly the same estimates, with far

less work, by making these corrections after-the-fact, to national aggregate data just prior to calculation of DRG weights?

I have not done a comparison between the full-detail approach used here and a simple aggregate correction. The methods would appear to be pretty straightforward, and would entail following the steps for the full-detail method, but using aggregate data. This would be the following:

- Summarize SAF supplies sub-category charges in total and by DRG.
- Determine a national average "standardization" factor for the supplies CCR. Multiply the regression-based adjustment by the share of charges in each sub-category, add, and then use this in the next step.
- Calculate budget-neutral sub-category CCRs, as the sum of the US supplies average CCR (0.33) plus the standardization factor plus the adjustment factors from the regression.
- Apply these budget-neutral supplies CCRs to the aggregate supplies charges for each DRG.
- Compare the supplies costs gotten this way (the "decompressed" cost, with separate CCRs for the sub-categories) to the supplies cost obtained in the traditional fashion (total supplies charges times overall supplies CCR).
- Use the resulting percent difference to adjust the cost-based DRG weights. For example, if the "decompressed" supplies cost for defibrillators (DRG 515, say) was 50 percent higher than the "compressed" cost, based on these aggregates, then take whatever supplies cost you were going to use for calculating the cost-based weight for that DRG, and increase it by 50 percent

4 CONCLUSION

This research has demonstrated a feasible approach to solving most of the issue of charge compression. Hospitals appear fairly good about using the correct revenue centers for report inpatient charges for expensive implantable devices. This, in turn, leads to a strong correlation between the mix of charges in the hospital and the CCR for supplies. Hospitals reporting a lot of implantable devices have higher CCRs, all other things equal. Regression analysis can be used to quantify this correlation and generate a reasonably stable and robust estimate of the variation in CCRs across those supplies sub-categories. The resulting national average CCRs by supplies sub-category can be used to estimate "decompressed" supplies costs on each claim record, factoring in a higher CCR for implantable devices and lower CCR for routine supplies. The resulting adjustment increases cost-based DRGs weight for device-intensive DRGs, notably defibrillator, pacemaker, spinal fusions, joint replacements, and stent implants.

This is not a complete solution. It is not a complete solution because it is limited by hospital data reporting, by the structure of the revenue center codes, and by the limitations of a regression-based approach. For certain key DRGs (such as ICD and pacemaker), hospitals largely (though not entirely) appear to report charges in the correct revenue centers. Some classes of implantables either cannot be separately identified by revenue center (or combination of revenue center and DRG), or constitute too small a fraction of charges and therefore will not generate stable estimates in a regression analysis. Perhaps some of these limitations can be improved through further research.

Nevertheless, this method addresses the issue of charge compression for several important categories of implantable devices, including defibrillators, pacemakers, joints, and to some degree stents. Further, it relies solely on Medicare administrative data to make the adjustment. On net, the resulting "decompressed" cost should result in more accurate payments than cost weights calculated without an adjustment for charge compression.

ATTACHMENT 5

June 7, 2006 Device Company Presentation to CMS on Charge Compression

Addressing Charge Compression for Implantable Devices

Medtronic, Johnson & Johnson, Boston Scientific,
and St. Jude Medical meeting with CMS
June 7, 2006

Agenda

- Introductions
- Recap of May 9 meeting on IPPS
- History of industry concerns with charge compression
- Evidence on existence of charge compression
- Potential approach to counterbalance effects of charge compression
- Policy recommendations on IPPS proposed rule

2

May 9, 2006 Meeting

- Companies raised concerns about:
  - Differences in CMS and MedPAC approach to HSRV and cost-based weights
  - Methodological flaws in CMS HSRVcc proposal
  - Policy concerns and overall accuracy of HSRV and cost-based weights
  - Technical concerns with CMS CS-DRGs
  - Timing of implementation
- Agreed to return with recommendations
  - Charge compression one of many issues that must be addressed
  - Today's recommendations start the work, but industry may identify/recommend additional refinements

3

Longstanding Concerns with Charge Compression

- Industry has worked with CMS for 6 years on charge compression in OPPS
  - Inaccurate estimates of costs a key barrier to long-term stability in OPPS
    - Payment rates for defibrillators (for example) thousands of dollars off
  - CMS has used external data and payment floors in the past, but no robust solution for the future
- Movement toward cost-based weights in IPPS will expand the problem of charge compression
  - Significant concern about patient access to therapies shown to represent substantial clinical improvement over current alternatives

4

Evidence on Existence of Charge Compression

- Numerous analyses over the past 6 years
- Today focus on:
  - Benchmarking charge mark-ups found in OPPS to external data on costs (IMS)
  - Evidence of charge compression from Medicare data & potential adjustment

5

Benchmarking of Charge Mark-Ups Found in OPPS to External Data on Costs

(See attached Moran Company slides)

6

Evidence of Charge Compression from Medicare Data & Potential Adjustment

7

Charge Compression: Issue

- **The issue: one average CCR for all supplies/devices**
  - Cost report has one line for all supplies/devices
  - Generates one CCR for all supplies/devices pooled
  - But numerous sources say markup is lower (CCR higher) for high-cost devices
  - So estimated cost (charge x average supply/device CCR) understates cost of high-cost devices, overstates routine supplies cost

8

Initial Analysis: Demonstrate Correlation Between CCR & Case Mix

- Use CMS data to show evidence of charge compression
- If - Then
  - If charge compression exists,
  - Then supplies CCR should vary systematically with supplies mix.
- Calculate fraction of cases in DRGs with high supplies charges
  - Three overlapping DRG categories based on national average supplies charges ($30K+, $20K+, $15K+, avg. supplies $ per case)
  - Find fraction of hospital cases in these DRGs
- Regress hospital supplies CCR on control variable and case mix
- Shows correlation and dose/response relationship (next slide)
- Did not translate into a workable policy approach
- Presented here to show that supplies mix affects supplies CCR

9

Initial Analysis: Hospital CCR as Function of Case Mix

Summary of Three Regressions: Hospital Supplies CCR as Function of % Cases in Supplies-Intensive DRGs		
Casmix Measure: % of cases in DRGs with	**Coefficient on Casemix Measure**	
	Coeff.	t-stat.
30K+ average supplies charge.	1.07	4.05
20K+ average supplies charge	0.62	3.96
15K+ average supplies charge	0.21	4.02
Source: Analysis of FY 2004 MedPAR and FY 2003 cost reports. Regression included constant and term for average hospital CCR excluding supplies.		

10

Second Attempt: Vary CCR by Supplies Revenue Center Code

- Revenue centers identify charges in key sub-categories:
  - Pacemaker/defibrillator, other implantable device.
  - Versus: general supplies, general sterile supplies
- Create and apply data-driven CCR adjustment for supplies sub-categories.
  - Regress supplies CCR on supplies mix to estimate average CCR variation across supplies sub-categories.
  - Use regression coefficients to adjust hospital supplies CCR.
  - Sub-category CCR = actual hospital supplies CCR + national average regression-based sub-category adjustment.
  - "Decompressed" cost = subcategory charges x sub-category CCRs.
  - Force budget neutrality in each hospital (total supplies cost constant)
  - Re-estimate DRG weights with "decompressed" cost.

11

Regression Analysis

- Sum hospital supplies chgs. by rev. center (5% SAF).
- Supplies mix: % of supplies chgs in 4 largest rev ctrs.
- Match to cost report to get supplies CCRs.
- Regress hospital supplies CCR on supplies mix variables plus control variable (CCR for ancillaries excl. supplies).
- Find large, stable, robust impact of charge mix on CCR.
- Best specification combines inpatient and outpatient charges (coincidentally matches data in cost reports).

12

Regression Results

Supplies CCR as Function of % of Supplies Charges by Sub-Category				
Variable	Coeff	Std Error	T-value	P-value
Intercept	0.108	0.027	3.91	<.0001
CCR, ancill. excl supplies	0.717	0.031	23.07	<.0001
pct_0270 (general supplies)	-0.049	0.027	-1.81	0.07
pct_0278 (implantables)	0.133	0.029	4.56	<.0001
pct_0272 (sterile supplies)	-0.025	0.032	-0.78	0.44
pct_0275 (pacemaker)	0.160	0.040	4.02	<.0001

Source: Analysis of 5% SAF 2004 inpatient and outpatient files matched to 2003 hospital cost reports.

Notes: Dependent variable mean is 0.33. Adjusted R-squared = 0.19. Number of observations is roughly 3,000. Regressions were weighted by supplies charges.

13

Average CCRs After Budget-Neutrality Adjustment

Estimated CCRs for Supplies Sub-Categories	
Supplies subcategory	Net average CCR after budget-neutrality adjustment
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29

Source: Analysis of 2004 5% standard analytic file and hospital cost report data

14

Highlights of Major Gains From Decompression

HSRVcc Weights

DRGs with 10K+ discharges, Ten Largest Weight Increases from Decompression									
				HSRVcc, incorrect (CMS) cost share			HSRVcc, correct cost share		
DRG	Short title	PPS Disch. 2005	2006 wgt	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
515	Defibrillator	57,279	5.52	4.15	4.69	13%	4.90	5.69	16%
552	Pacemaker	80,797	2.10	1.77	1.94	10%	1.97	2.23	13%
551	Pacemaker	53,077	3.10	2.63	2.82	7%	2.87	3.15	10%
498	Spinal fusion	21,188	2.78	2.53	2.64	4%	2.81	3.01	7%
497	Spinal fusion	30,517	3.62	3.33	3.48	5%	3.66	3.90	7%
520	Spinal fusion	16,310	1.68	1.47	1.52	3%	1.63	1.72	5%
471	Hip/Knee	15,407	3.14	2.74	2.91	6%	3.11	3.27	5%
491	Shldr/Elbow	22,356	1.68	1.60	1.64	2%	1.74	1.82	4%
545	Hip/Knee	43,873	2.48	2.41	2.48	3%	2.60	2.71	4%
558	PTCA w DES	189,047	2.21	1.43	1.49	4%	1.75	1.84	5%

15

Highlights of Major Gains From Decompression

Traditional Cost Weights

DRGs with 10K+ discharges, Ten Largest Weight Increases from Decompression									
			Traditional cost weight with HSRV			Traditional cost weight, standardized			
DRG	Short title	PPS Disch. 2005	As Is	De-com pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss	
515	Defibrillator	57,279	5.03	5.81	16%	5.17	5.93	15%	
552	Pacemaker	80,797	2.01	2.26	13%	2.04	2.29	12%	
551	Pacemaker	53,077	2.92	3.20	9%	2.98	3.25	9%	
498	Spinal fusion	21,188	2.87	3.08	7%	2.99	3.20	7%	
497	Spinal fusion	30,517	3.72	3.97	7%	3.88	4.12	6%	
520	Spinal fusion	16,310	1.65	1.74	5%	1.69	1.78	5%	
471	Hip/Knee	15,407	3.11	3.28	5%	3.22	3.38	5%	
491	Shldr/Elbow	22,356	1.73	1.80	4%	1.75	1.82	4%	
545	Hip/Knee	43,873	2.58	2.68	4%	2.62	2.72	4%	
558	PTCA w DES	189,047	1.81	1.88	4%	1.85	1.91	4%	

16

Highlights of Major Losses From Decompression
HSRVcc Weights

DRGs with 10K+ discharges, Ten Largest Weight Reductions from Decompression									
				HSRVcc, incorrect (CMS) cost share			HSRVcc, correct cost share		
DRG	Short title	PPS Disch. 2005	2006 wgt	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
547	CABG	32,200	6.20	5.69	5.57	-2%	5.88	5.72	-3%
549	CABG	12,849	5.10	4.88	4.77	-2%	4.98	4.84	-3%
548	CABG	31,647	4.72	4.18	4.06	-3%	4.38	4.24	-3%
216	Musc. Biop.	19,770	1.91	1.72	1.67	-3%	1.78	1.72	-3%
335	Pelv Proc	12,001	1.10	1.07	1.04	-3%	1.12	1.06	-3%
550	CABG	34,049	3.62	3.46	3.35	-3%	3.57	3.44	-3%
518	PTCA no stent	23,425	1.65	1.14	1.10	-3%	1.37	1.32	-3%

17

Highlights of Major Losses From Decompression
Traditional Cost Weights

DRGs with 10K+ discharges, Ten Largest Weight Reductions from Decompression								
			Traditional cost weight with HSRV			Traditional cost weight, standardized		
DRG	Short title	PPS Disch. 2005	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
547	CABG	32,200	5.85	5.69	-3%	5.95	5.78	-3%
549	CABG	12,849	4.94	4.81	-3%	5.06	4.91	-3%
548	CABG	31,647	4.40	4.26	-3%	4.48	4.33	-4%
216	Musc. Biop.	19,770	1.77	1.71	-3%	1.83	1.77	-3%
335	Pelv Proc	12,001	1.10	1.07	-3%	1.11	1.08	-3%
550	CABG	34,049	3.56	3.44	-3%	3.64	3.50	-4%
518	PTCA no stent	23,425	1.42	1.37	-4%	1.45	1.39	-4%

18

Summary

- Use statistical analysis to estimate average CCRs for supplies sub-categories
  - Hospital-level, predict supplies CCR as function of supplies mix.
  - Relies on hospital coding of charges by revenue center
  - Relies on strong average relationship between supply mix and CCR.
  - Statistical (regression) analysis appears robust
  - Size of adjustment appears reasonable (vis-à-vis IMS data).
- Calculate costs for supplies sub-categories, force budget-neutrality.
  - Sub-category CCR = supplies CCR + sub-cat. factor from regression.
  - Sub-category cost = sub-category charges x sub-category CCR.
  - Make budget-neutral within each hospital (total supplies cost constant).
- Raises weights for device-intensive cardiac, orthopedic DRGs.
- Only works for some major supplies categories.
  - E.g. IOLs are too small as % of supplies charges.
- But could be further refined
  - Cardiac versus orthopedic implantables (split by MDC)
  - Sub-categories of cardiac (stent versus pacemaker/ICD), split by DRG.
  - Screen hospitals for correct coding of charges (as in OPPS).

19

Policy Recommendations on IPPS

20

1. Timing of Implementation

- Fully support goal of improving payment accuracy in the DRG system
  - Payments should match costs as closely as possibly
  - Inpatient procedures should be neither overpaid nor underpaid
- But scope of issues with HSRVcc and CS-DRGs too large to be addressed during comment period
  - Inadequate opportunity for review of alternatives that may appear in final rule
- CMS should defer implementation until FY 2008
  - Sufficient time for further analysis and development of broader consensus

21

2. HSRV and Cost-Based Weights

- Replace HSRVcc with traditional cost-based weights (OPD-style) and no HSRV
  - 10 national cost-center approach exacerbates charge compression (methodological flaws worsen problem)
  - HSRV questionable policy with cost-based weights
    - Unnecessary change since current standardization policy adjusts for differences due to wage levels, teaching and disproportionate share
      - Fails to consider natural variation in cost that may occur between hospitals
    - Reduces range of variation between low and high DRG weights
    - Disproportionate impact on certain types of hospital and certain types of care (surgical cardiac)
- Traditional cost-based weights alone (OPD-style) most appropriate way to address payment accuracy

22

3. Improve Accuracy of Underlying Cost Information

- Concurrent with transition to cost-based weights, cost report information and charge compression must be addressed
- Cost Reports
  - CMS convene expert panel to identify methods to better use information from hospital cost reports for appropriate use in the inpatient and outpatient PPS weight-setting processes.
  - Panel must report back with recommendations by March 31, 2007.
- Charge Compression
  - Develop adjustment to ensure implantable devices do not get reduced below cost in weighting systems that rely on converting charges to costs
  - Opportunity to address inpatient and outpatient PPS

23

4. Severity DRGs

- Develop severity-adjusted DRGs using the existing CMS DRG system
  - CS-DRGs based on APR-DRGs do not reflect changes made to the Medicare DRG system in last two decades
  - Using APR-DRGs as the starting point results in numerous DRG mismatches and abrupt payment shifts unrelated to matching payments to higher severity patients in current DRG system
  - CMS should use the existing Medicare DRGs as the starting point for any severity-related changes.
    - All DRGs or selected ones
    - Consistent with FY 2006 refinements

24

5. Transition

- Implement cost-based weights and severity DRGs jointly to avoid sharp payment fluctuations from year to year
- Assuming all issues can be addressed, implementation should begin in FY 2008
  - Phase in over 3-4 years
    - Increasing blend of cost and charge weights
  - Adjustments for charge compression to accompany institution of cost-based weights
- Improvements in the use and accuracy of cost reports should be developed and implemented during the transition period

25

Thank You

ATTACHMENT 6

Issues in the Use of Medicare Cost Reports to Calculate DRG Relative Weights

ISSUES IN THE USE OF MEDICARE COST REPORTS TO CALCULATE DRG RELATIVE WEIGHTS

June 5, 2006

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1. INTRODUCTION

On April 13, 2006, the Centers for Medicare and Medicaid Services (CMS) published proposed regulations that described significant modifications to the Medicare Inpatient Prospective Payment System (IPPS). Since the introduction of the IPPS, relative weights for the system's Diagnostic Related Groups (DRGs) have been based on hospital charges. The proposed regulations describe CMS' intention to use cost-based relative weights to replace the charge-based approach. Use of cost-based weights will have a significant impact on payments for certain DRGs and, as a result, will have a substantial effect on hospitals.

The impact of the change to cost-based weights on payments to hospitals is the subject of other reports. In general, the use of cost-based weights will result in compression of relative weights, i.e., there will be less difference among weights across DRG categories. More specifically, the relative weights for relatively complex DRGs (especially surgical DRGs) will decline and the relative weights for less complex DRGs (especially medical DRGs) may increase. Although the impact of the changes is discussed elsewhere, some of the key reasons for the changes are discussed in this report.

CMS' cost-based weights are calculated by applying cost to charge ratios reported in hospital Medicare Cost Reports to charges for specific cases. The approach assumes that the cost data in the Medicare Cost Report is an accurate representation of the costs of individual cases. This issue and other related issues are examined in this report. The report includes discussions that address CMS' approach to calculating cost-based weights, the history and purpose of the Medicare Cost Report, problems in the use of the Medicare Cost Report to calculate DRG relative weights, specific findings on the impact of CMS proposed cost-based weights on a set of key cardiac DRGs and recommendations for improving the Medicare Cost Report so that it can be used to calculate relative weights that are more accurate.

2. THE CMS APPROACH TO CALCULATING COST-BASED RELATIVE WEIGHTS

The approach used to calculate departmental costs in the Medicare hospital cost report is at the heart of the CMS approach to calculating cost-based DRG relative weights. The costs calculated in the cost report are used to calculate cost to charge ratios (CCRs), which, in turn, are applied to claims data to support the calculation of a relative weight for each DRG.

CMS, acting upon MedPAC's recommendation, created a methodology to calculate a cost-based hospital specific relative-value (HSRV) that is less complex than that created

by MedPAC. The CMS method involves developing hospital-specific charge-based relative weights at the cost center level to remove the bias introduced by hospital characteristics, such as teaching, disproportionate share, location and size. These weights are then scaled to a facility's costs using national cost center cost to charge ratios, which CMS develops using cost report data. CMS identified ten cost center categories to be used in this calculation. These categories include eight ancillary cost groups plus routine care costs and intensive care costs. The categories were created to properly segment data without overly representing any one area; therefore each category represents at least five percent of charges in the claims data. CMS then uses these cost center groupings to create national average CCRs; these estimated costs are used to develop cost-based relative weights. A more detailed description of this process follows.

Step One: *Cleaning the Data*

CMS grouped all claims using Version 23.0 of the CMS DRGs. Hospitals without cost report data had their claims excluded from the analysis. Similarly, claims with a length of stay less than or equal to zero, as well as those with total charges differing greatly from the sum of their charges for major cost centers were eliminated. Finally, all statistical outliers beyond 3.0 standard deviations from the mean were excluded.

Step Two: *Compute HSRVs for Each Cost Center for Each DRG*

Average charges were calculated for each provider for each of the ten identified cost centers by summing charges in each cost center and dividing by the transfer-adjusted count for each provider. By claim, each cost center's charges were divided by the provider's average charge for the matching cost center across all services to calculate relative charges. CMS then adjusted these charge weights by the provider's CMI. Both relative charges and transfer adjusted case counts were summed by DRG. CMS then determined the average cost by DRG by dividing these summed relative charges by the summed transfer-adjusted case count.

Using MedPAR data, a national average charge for each cost center was calculated by dividing the sum of relative CMI-adjusted charges by the total transfer-adjusted case count. This allowed for "cost center DRG weights" to be created by dividing national average charge for each DRG for each cost center by the national average charge for that cost center. This produced ten weights for each DRG that could be assigned to each claim in turn producing a new CMI for each provider. CMS applied iterations of analysis to this CMI to ensure the national average CMI did not fluctuate.

Step Three: *Compute CCRs from the Cost Reports for Each of the Ten Cost Center Groups Identified*

CMS worked to remove markup differences that exist in certain cost centers by developing national cost center CCRs. A similar analysis as described in Step One applies to their creation of these CCRs. In the end, a geometric mean CCR was determined for each cost center group.

Step Four: *Sum the Average Charge for Each Cost Center from the MedPAR Data and Apply the National CCRs from the MedPAR Files*

Using the national average CCRs from Step Three and total unadjusted charges for matching cost centers in the MedPAR file, CMS determined an estimated cost for each claim. These costs were then summed to produce the total cost for all cases across the nation. The center's overall costs were divided by total costs to calculate a scaling factor for each cost center.

Step Five: *Adjust Relative Weights from Step Two to Cost by Applying Scaling Factors from Step Four*

The scaling factors from Step Four multiplied by the cost center weights from Step Two produce a single final weight for each DRG.

Step Six: *Normalize the Weights*

To accurately compare the results from Step Five with the charge-based weights in effect during FY 2005, each DRG weight must be normalized using the normalization factor of 1.47462. This is the factor applied to FY 2006 charge-based weights to ensure that total payments under IPPS neither increase nor decrease.

To a considerable extent, the accuracy of cost-based relative weights depends on the accuracy of the costs in the Medicare hospital cost report. The cost report, however, was not designed to measure case-specific costs. Instead, as discussed in the next two sections, it was designed to measure a hospital's aggregate allowable cost as defined by Medicare regulations.

3. HISTORY AND PURPOSE OF THE MEDICARE HOSPITAL COST REPORT

As discussed subsequently, the Medicare hospital cost report is an inadequate tool for the calculation of DRG payments. The cost report was developed to support the cost reimbursement approach that was established when the Medicare program was enacted in 1967. Medicare's enabling legislation required the program to pay hospitals for the cost of caring for Medicare patients. Cost reimbursement had been used for some time by several Blue Cross plans prior to the passage of Medicare. The approach adopted for the Medicare program was based on the Blue Cross approach, which required hospitals to prepare and submit annual reports on their costs. The reports were designed to determine the total annual reimbursement due to a hospital for serving a plan's subscribers. Hospitals were paid interim amounts based on an estimate of the total

annual amount to be paid and a retrospective settlement was completed after the cost report was submitted and audited.

The Medicare program adopted the Blue Cross approach, but modified it to reflect the difference between its definition of allowable cost and the Blue Cross definition of allowable cost. The Medicare definition was based on the definition outlined in legislation and regulations while the Blue Cross definition was based on plans' contracts with hospitals.

Despite the differences in definitions of allowable cost, the concepts underlying hospital cost reports were identical for Blue Cross and Medicare. In general, determination of the amount to be paid by a payer using cost reimbursement was based on the following principles:

- Total hospital costs were reported based on the accounting records of the hospital, prior to any adjustments in the definition of allowable costs. These costs are presented in the form of the hospital's final trial balance which is completed to support the preparation of financial statements. The trial balance is the final balance in each of the hospital's general ledger accounts at the end of the fiscal year.
- Adjustments to the trial balance based on the definition of allowable costs are identified. For example, Medicare has never paid for certain costs, such as marketing costs, bad debts and the costs of certain professionals who are paid independently by the program.
- The adjusted trial balance was used to determine costs for each cost center. This determination requires two steps: assignment of direct costs to cost centers and the allocation of indirect costs to revenue centers. When these two steps are completed, an estimate of the total costs associated with each revenue center was calculated.
- Total costs associated with each revenue center were then compared to total charges for that revenue center to arrive at a cost to charge ratio. This ratio measures the relationship between costs and charges for each revenue center.
- Cost to charge ratios were then applied to charges for the payer's patients and an estimate of the cost of caring for those patients was calculated.
- Other costs, such as the costs of indirect medical education, were added to the costs determined by applying cost to charge ratios. Additional reporting requirements were added (financial statements), but the key elements of determining reimbursement are identified in the steps that have been listed.

The costs paid by the Medicare program under cost reimbursement are aggregate estimates that are derived by using the principles that have been described. The

accuracy of the cost determination conventions used in the cost report was assumed. The Medicare program believed that its cost report approach provided a sufficiently accurate measure of aggregate costs incurred by each hospital in serving Medicare patients. The program did not use cost report data to calculate the costs associated with serving specific patients.

As discussed in subsequent sections, an understanding of the methods used in the cost report to calculate aggregate costs is critical to understanding the limitations of the approach when it is used to calculate DRG relative weights.

4. PROBLEMS IN THE USE OF THE MEDICARE COST REPORT TO CALCULATE DRG RELATIVE WEIGHTS

As noted previously, the accuracy of the Medicare program's DRG relative weights depends on the accuracy of the costs reported in the Medicare cost report. The cost report, however, is not a useful source for the calculation of costs in today's hospital payment environment. The limitations of the Medicare cost report as a cost determination tool are well documented in the literature. In an article published in the *Healthcare Management Review*, Magnus and Smith identified several studies conducted over the past two decades that document a variety of issues and shortcomings related to the MCR and its use in health policy decisions[1], including:

- The Prospective Payment Assessment Commission (ProPAC), which was succeeded by the Medicare Payment Advisory Commission (MedPAC), found that the Medicare hospital cost report does not recognize a broad range of indirect costs of providing patient care, even though widely accepted accounting methods would include these expenses. These expenses include the costs of charity care and bad debts, malpractice insurance, growth in working capital and related interest expense, marketing and recruitment costs, investments in cost-saving initiatives, costs for the preparation of the cost report, and patient amenities such as telephones and access to television.
- ProPAC also found that the cost report arbitrarily limits the compensation of hospital-based clinicians, and does not encourage the most accurate method of cost finding.
- Cleverley, in a study of voluntary versus investor-owned hospitals, found that hospitals have had incentives over the years to prepare cost reports to enhance Medicare reimbursement and may have shifted costs by reassigning debt, expenses, and assets among the individual hospitals that comprise multi-hospital systems.

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[1] Magnus SA and Smith DG. "Better Medicare Cost Report Data are Needed to Help Hospitals Benchmark Costs and Performance." *Healthcare Management Review*, Vol. 25., No. 4, Fall 2000.

- Johnsson and colleagues found that individual hospital cost reports tend to overstate costs and to minimize profitability in order to maximize cost recovery. In addition, Medicare guidelines allow for a wide range of acceptable cost accounting practices, which makes it difficult to compare costs across hospitals as well as individual departments within hospitals.
- Ashby and other ProPAC staff found evidence of sophisticated cost shifting among hospitals that may be difficult to detect in the cost report. In the same study, Ashby and colleagues also found that some of the cost report's cost-finding methodologies are inaccurate, which causes variation in the validity of specific DRG costs. Ashby also observed that while total Medicare inpatient costs in the cost report are reasonably reliable, when separated into routine inpatient and ancillary costs, they become less reliable, and that cost report data should not be used for measuring micro-level costs.
- In separate studies, Hwang and Kirby, and Gianfrancesco described how patient days are used to allocate inpatient care costs in the cost report rather than multiple other cost drivers, resulting in distortions in overall costs.

Magnus and Smith contend that the research efforts they reviewed provide evidence that the cost report should be more closely scrutinized as a source of data on the true costs of individual hospitals and that certain conclusions drawn solely from data contained in cost reports should be viewed "skeptically."[2]

In another study by Magnus and Kane, the authors found that many cost report measures of cost, including operating and nonoperating expenses, are not consistently defined or separated. For example, the authors found that one hospital in the study recorded a $5 million onetime payment to its medical school as an operating expense in its cost report but as a nonoperating expense in its audited financial statements, resulting in a two percent discrepancy in the hospital's operating margin. The researchers cite several other deficiencies in the cost report, including issues regarding the accurate reporting of revenues and expenses. They conclude that the "financial accounting elements in the Medicare cost report are unreliable, poorly defined and lacking in critical detail" and that "Medicare cost report financial data give only a limited and often inaccurate picture of the financial position of hospitals."[3]

A study conducted by the Rural Policy Research Institute (RUPRI) Center for Rural Health Policy Analysis found differences in the information in Medicare cost reports and audited financial statements among hospitals. The study included comparisons of fourteen financial ratios for rural non-critical access hospitals as reported in the hospitals' cost reports and audited financial statements. For forty percent of hospitals in the study, researchers found that total hospital margin differed by more than five

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[2] Ibid.

[3] Kane NM and Magnus SA. "The Medicare Cost Report and the Limits of Hospital Accountability: Improving Financial Accounting Data." *Journal of Health Politics, Policy and Law*, Vol. 26, No. 1, February 2001.

percent between cost reports and audited financial statements. The researchers concluded that because of these differences, Medicare cost reports should not be used as a single source of data for assessing the financial performance of rural hospitals.[4]

Limitations of the cost report were also documented in studies conducted by Miller for the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (OASPE) and for ProPAC.[5] These studies focused on the variation in methods used by hospitals to assign direct costs and allocate indirect costs to revenue centers. The studies found that differences in accounting among hospitals provided considerable opportunity for variances in reporting to occur. In the 1983 OASPE study, assignment of direct costs and allocation of indirect costs were measured prior to the implementation of the IPPS. During the period of this study, hospitals had incentives to report higher inpatient costs because Medicare was the primary payer using the Medicare cost report for cost reimbursement and the Medicare program paid a considerably higher portion of inpatient costs than outpatient costs. Study findings indicated that hospitals used cost assignment and allocation methods to respond effectively to this incentive. In the 1989 OASPE study, assignment of direct costs and allocation of indirect costs were studied in the same hospitals, five years after the introduction of the IPPS. During the period of this study, the Medicare program no longer used cost reimbursement to pay hospitals for inpatient services, but retained its use to pay for outpatient services provided to Medicare patients. Study findings indicated that hospitals that had used cost assignment and allocation methods to increase inpatient payment in 1982 were able to use similar principles to increase outpatient payments. The findings also indicated that the ability of hospitals to manipulate costs reported in the cost report implied that there was sufficient variance in the measurement of cost to question the accuracy of the costs of individual cost centers.

The ProPAC study completed by Miller in 1992 addressed the accuracy of departmental costs reported in the cost report more directly. In this study, DRG-specific costs calculated by more than thirty hospitals that used sophisticated cost accounting systems for internal reporting were compared to DRG-specific costs derived using Medicare cost reporting principles for the same hospitals. The cost accounting systems used standard costing based on management engineering studies conducted to determine the precise inputs used in specific services and the costs of those inputs. Study findings identified substantial variances between costs calculated by hospital cost accounting systems and costs calculated using Medicare cost reports which led to the conclusion that the Medicare cost report did not necessarily provide accurate measures of cost, especially when it was used to calculate the costs of specific services.

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[4] Chen L, et.al. "An Analysis of the Agreement of Financial Data Between the Medicare Cost Report and the Audited Hospital Financial Statement." *Rural Policy Brief*, Vol. 9, No. 4, May 2004.

[5] Miller, H.. *Evaluation of Methodologies to Measure Hospital-Based Ambulatory Care Costs*, (Center for Health Policy Studies, Columbia, MD, 1983); *Replication of 1982 Study of Resource Use Costs in 25 Hospitals*, (Center for Health Policy Studies, 1989) and *Evaluation of the Use of Medicare Cost Reports as a Research and Policy Analysis Tool*, (Center for Health Policy Studies, 1992).

Although the literature has identified limitations in the accuracy of Medicare cost reports when they are used for purposes other than the determination of Medicare allowable cost, it is important to understand the underlying causes of these limitations. Inaccuracies in the determinations of departmental or service-specific costs in cost report data are caused by a lack of uniformity in the accounting and allocation principles used by hospitals. In addition, cost reporting principles calculate aggregate costs at the departmental level without regard for the differences in hospital charge setting practices within cost centers. Both of these issues are discussed in the paragraphs that follow.

The steps used in the Medicare cost report to calculate revenue center cost to charge ratios were outlined in Section 3 of this report. Each step provides opportunities to introduce inaccuracies in calculations. In summary, these steps are:

- Total hospital costs are reported in worksheet A, based on the accounting records of the hospital, prior to any adjustments in the definition of allowable costs. These costs are presented in the form of the hospital's final trial balance.
- Adjustments to the trial balance based on the definition of allowable costs are identified in supplements to worksheet A.
- The adjusted trial balance is used to determine each cost center's costs. This determination requires two steps: assignment of direct costs to cost centers and the allocation of indirect costs to revenue centers.
- Total costs associated with each revenue center are compared to total charges for that revenue center to arrive at a cost to charge ratio.

Accounting is far less precise than is generally assumed by non-accountants. Accountants use their judgment to classify assets, liabilities, revenues and costs. This judgment must be applied in the context of Generally Accepted Accounting Principles (GAAP), but GAAP allows for considerable variation in the recording of accounting information. The cost report focuses on the classification of costs. Worksheet A is the product of a year long effort by a hospital's accounting staff to identify and classify costs as they occur. In most instances, costs are readily classified, such as salaries paid to nurses. In some instances, however, judgment must be applied. For example, if a hospital incurs costs to repair its facility, the costs are normally recorded as "Repairs and Maintenance Expense", the term that is typically used for the related expense account in the hospital's general ledger. If the repairs are extensive and intended to improve the facility for more than one year, they may be treated as an addition to assets rather than as an expense. If a portion of the expenditure will have a long-term effect and another portion is for routine repairs, the amount of the expenditure may be split between the asset and the expense account. Although there are rules governing the amortization of assets and other rules that require minimum standards for capitalizing the value of repairs, the decision on how to treat such an expenditure is based on the management's

judgment. Different people faced with the same set of facts may reach different conclusions, based on their perceptions. As a result, there is far less uniformity in the definitions used to prepare the trial balance than may be assumed.

The variations that are inherent in the trial balance are the initial point at which departmental and service-specific costs may be distorted. The adjustments to the trial balance that are made in the cost report to eliminate costs that are not allowed by the Medicare program can have a far greater impact. As was noted in the review of the cost report literature, costs such as marketing, recruiting, charity care, bad debts and malpractice insurance are removed from the account balances in the trial balance because they are not allowed by the Medicare program although they are real costs incurred by hospitals and are included in hospitals' financial statements.

The distribution of the adjusted trial balance's costs to cost centers, which is completed in Worksheet B, is a significant limitation of the cost report when it is used to determine other than aggregate hospital costs. Direct costs are assigned to cost centers based on how they are recorded during the year. The rules for assigning costs vary by hospital and by activity. For example, although it seems obvious that salary costs of nurses engaged in routine inpatient care will be assigned to routine care, variations in such assignments occur frequently. If a nurse spends a portion of his or her time in routine care and a portion in the ICU, salaries should be allocated proportionately. Nevertheless, many hospitals do not track such movement among nurses and will assign all of the costs to the revenue center that is designated for the nurse. Although a portion of the nurse's time should be charged to the ICU, it is highly likely that all of the nurse's salary will be charged to routine care. Problems in cost assignment are pervasive. If one hospital has a single cost center for housekeeping, it will record all relevant costs in that cost center and then allocate them as part of the cost allocation process. If, however, a hospital decentralizes housekeeping services, costs associated with housekeeping for a specific department may be treated as direct costs for that department. Similarly, some hospitals allow departments to purchase medical supplies, while all other supplies are purchased centrally. Depending on the hospital's accounting system, the supplies purchased by departments may be recorded as a direct expense of the department or as part of the cost of Central Supplies, which is allocated across departments. In the OASPE studies conducted by Miller, there was considerable variation in the approaches used by hospitals to assign costs to departments.[6]

Worksheet C is used to allocate indirect costs to revenue centers. Indirect costs are incurred by all cost centers for which hospitals do not set charges. Indirect cost centers include housekeeping, maintenance, utilities, administration and several other areas of hospital activity. These costs are allocated to revenue centers based on a variety of formulae that are intended to provide the most accurate distribution of costs. Despite

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[6] See Miller, op.cit.

this intent, there are variations in the methods used by hospitals. In fact, there are cost centers for which there is no precise way to determine which allocation basis should be used. Some allocation bases are obvious, such as the allocation of utilities costs based on the square feet occupied by revenue centers. Allocation of administrative costs is far less obvious and as a result, hospitals can use different allocation bases to distribute administrative costs, including number of FTE personnel in each revenue center, total revenue center costs prior to the allocation of administrative costs or total salary costs.

Each of the issues that have been raised contributes to limitations in the use of cost reports to calculate costs of revenue centers. An additional limitation must be considered when cost center data are used to calculate cost to charge ratios and these ratios are applied to the calculation of DRG relative weights. The ratio that is calculated assumes a constant relationship between costs and charges for all costs included in the cost center. For example, application of a cost to charge ratio for supplies to all supplies assumes that a hospital has a common markup for all supplies, although it is clear that markups vary greatly. The impact of this problem is obvious. If it is assumed that a hospital's cost to charge ratio for the Medical Supplies revenue center is 0.25 but the markup for a specific Medical Supplies item is only two times cost for an item that has a charge of $6,000.00 and the item is the only supply item used for the DRG, the cost for Supplies associated with the DRG will be $1,500.00 rather than the actual cost of $3,000.00.

Varying direct cost assignments, use of varying cost allocation bases and the assumption that markups are uniform within a revenue center significantly affect the accuracy of costs per unit of service that are calculated using cost to charge ratios. Although the approach is sufficient to meet the original purpose of the cost report, i.e., calculation of Medicare reimbursable cost, it does not provide accurate data for the calculation of unit costs or for setting DRG weights.

5. COMPARISON OF COSTS CALCULATED USING MEDICARE COST REPORT DATA AND COSTS MEASURED USING HOSPITAL COST ACCOUNTING SYSTEMS

It is critically important to understand the extent of the impact of using the CMS approach to calculating and applying cost to charge ratios in the development of DRG weights. Cost accounting data were collected from a sample of hospitals to investigate this impact. We sought a geographically dispersed hospital sample that included a range of hospitals by size. All hospitals selected were required to be using a cost accounting system that was based on standard costs and not cost to charge ratios. We were especially interested in a specific set of cardiac DRGs and therefore, focused on hospitals that provided those services. Our ability to collect data was significantly limited by the time available to respond to the proposed regulations. The specific DRGs of interest are listed in Appendix A and the hospital sample, which includes 22

hospitals, is identified in Appendix B. The 22 hospitals reported costs for 7,552 cases in the DRGs of interest. Our data collection and analysis approach is presented below. We were especially interested in measuring actual costs for each selected DRG and comparing these costs to the Medicare DRG payment that had been made in the past and that which would be made under the proposed regulations.

Our findings are presented in two primary comparisons; a comparison of the cost per case by DRG based on cost accounting data compared to cost per case calculated using cost-to-charge ratios. The second comparison is an estimate of the profitability by DRG based on comparing Medicare payments for specific DRGs to hospital costs for these DRGs derived from hospital cost accounting systems. In both instances, comparisons were made for the same period, i.e., the cost accounting data was collected for the period that matched hospital fiscal years used for cost reports.

Data Analysis and Preparation

Our data analysis consists of four calculations to prepare information for our comparisons presented in the following section.

Step One: Develop cost per case from cost accounting data. Using the data collected from the cost accounting system at each hospital, actual costs were categorized as: Routine, OR, ICU, Supplies, Drugs, Lab, X-ray and other. Costs were allocated to each of these designations by the cost accounting system's pre-established definitions, which are based on revenue codes. Each hospital also provided the total cost and number of cases for each DRG, which allowed for the cost per case to be calculated.

Step Two: Develop cost-to-charge ratios. We calculated cost to charge ratios using the most recent Medicare Cost Report data for each facility from the Healthcare Cost Reporting Information System (HCRIS). We used HCRIS data to obtain costs and charges by revenue center and by facility. These revenue center costs and charges were combined into broader categories as defined below:

Table 6A - Revenue Center Cost and Charges Grouping	
Category	Revenue Center
Drugs	Intravenous Therapy; Drugs Charged to Patients
ICU / CCU	Intensive Care Unit; Coronary Care Unit; Burn Intensive Care Unit; Surgical Intensive Care Unit; Other Special Care Unit (specify)
Lab	Laboratory; Whole Blood & Packed Red Blood Cells; Blood Storing, Processing, & Trans.
OR	Operating Room; Anesthesiology; Recovery Room
Routine	Adults and Pediatrics (General Routine Care); Nursery; Skilled Nursing Facility
Supplies	Medical Supplies Charged to Patients
X-Ray	Radioisotope; Radiology-Diagnostic; Radiology-Therapeutic
Other	Occupational Therapy; ASC (Non-Distinct Part); Renal Dialysis; Electroencephalography; Speech Pathology; Other Ancillary (specify); Delivery Room and Labor Room; Physical Therapy; Respiratory Therapy; Electrocardiology

After combining revenue center costs and charges in appropriate categories, cost-to-charge ratios were calculated by category and by facility.

Step Three: Calculate costs using MEDPAR data. We used the 2004 Medicare Provider Analysis and Review ("MEDPAR") file to obtain inpatient charges by facility, DRG and revenue center. Charges by revenue center were then cross-walked to the appropriate cost report revenue center / category where charges were accumulated by facility, DRG and category. Using the cost-to-charge ratios developed in the first step, cost-to-charge ratios were applied to the accumulated MEDPAR data at the facility and category level to compute facility specific costs by category and DRG.

Step Four: Calculate Medicare payments by DRG. The Medicare DRG payments to each hospital were calculated using the predefined payment formula established by CMS. This equation derives the Prospective Payment System (PPS) Operating Payment and Capital Payment for each facility using IME, DSH and other publicly available factors. Medicare's payments were estimated for 2004 using that year's charge-based relative weights and for 2007 using the new cost-based relative weights.

Findings

As previously noted, we completed two analyses: first, we compared costs based on hospital cost accounting data to costs based on cost to charge ratios, by DRG, for each hospital in our sample. Second, we compared the profitability of each DRG based on comparing actual cost to DRG payments using the 2004 charge-based weights and the cost-based weights as developed by CMS and published in the proposed rule.

Our analyses yielded two major findings. First, we found differences in costs calculated using cost accounting data compared to costs calculated using cost to charge ratios. More importantly, the differences were significant and consistent. Costs calculated using cost to charge ratios were substantially lower than costs reported in hospital cost accounting systems for all six of the cardiac DRGs of interest. The percent difference in costs averaged 28.8 percent. It is apparent that the use of cost to charge ratios to calculate costs consistently and significantly understates costs for DRGs that include implantation of pacemakers and defibrillators. The findings are presented in Table 5.2.

Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk	$ 22,291	$ 16,740	$ 5,551	25%
116 Oth Perm Cardiac Pacemaker Impla	$ 15,438	$ 11,069	$ 4,369	28%
118 Pacemaker Dev Replacement	$ 12,160	$ 8,265	$ 3,895	32%
515 Cardiac Defib Impl W/O Cath	$ 35,511	$ 25,347	$ 10,164	29%
535 Car Defib Impl w Cath AMI	$ 47,089	$ 33,165	$ 13,925	30%
536 Car Defib Implant wo AMI	$ 41,602	$ 29,570	$ 12,032	29%

Second, we calculated profitability for each of the same DRGs by calculating payments based on 2004 charge-based weights and comparing them to 2004 hospital costs, measured using cost accounting data. As can be seen in Table 5.3, hospitals are incurring substantial losses for each of the cardiac DRGs of interest under CMS' current charge-based approach for calculating DRG weights.

When we calculated profitability based on the cost-based weights in the proposed rule, losses on cardiac DRGs increased from an average of 20.0 percent for charge-based weights to an average of 38.2 percent under the proposed cost-based weights. If the intent of the proposed rule is to reflect costs of hospital services in payment amounts, the cost-based DRG weighting methodology falls far short of this intent. The findings are presented in Tables 5.3 and 5.4.

Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk	$ 18,410	$ 22,291	$ (3,881)	-17%
116 Oth Perm Cardiac Pacemaker Impla	$ 12,246	$ 15,438	$ (3,192)	-21%
118 Pacemaker Dev Replacement	$ 8,352	$ 12,160	$ (3,808)	-31%
515 Cardiac Defib Impl W/O Cath	$ 27,703	$ 35,511	$ (7,808)	-22%
535 Car Defib Impl w Cath AMI	$ 41,781	$ 47,089	$ (5,308)	-11%
536 Car Defib Implant wo AMI	$ 32,587	$ 40,163	$ (7,576)	-19%

DRG	Payment	Cost	Difference	% Difference
Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk**	$ 13,673	$ 22,291	$ (8,618)	-39%
116 Oth Perm Cardiac Pacemaker Impla**	$ 9,173	$ 15,438	$ (6,265)	-41%
118 Pacemaker Dev Replacement	$ 7,185	$ 12,160	$ (4,975)	-41%
515 Cardiac Defib Impl W/O Cath	$ 21,466	$ 35,511	$ (14,045)	-40%
535 Car Defib Impl w Cath AMI	$ 30,513	$ 47,089	$ (16,576)	-35%
536 Car Defib Implant wo AMI	$ 27,018	$ 40,163	$ (13,145)	-33%

** Several DRGs were reorganized in the proposed rule. Under the proposed rule, cases that were grouped in DRG 115 are grouped in DRG 551; cases that were grouped in DRG 116 are grouped in DRG 552.

The use of cost report data results in substantial inaccuracies in the calculation of costs of specific DRGs. When costs based on cost reports are compared to actual costs measured by hospitals for the DRGs that were studied, differences as great as 41 percent were measured with an average difference of approximately 30 percent. These differences increase losses already incurred by hospitals for many of the DRGs studied. If the proposed cost-based weights are implemented, hospitals will receive as little as 60 percent of their costs for some DRGs.

6. RECOMMENDATIONS TO IMPROVE THE MEDICARE COST REPORT'S VALUE AS A TOOL FOR CALCULATING DRG RELATIVE WEIGHTS

The Medicare cost report was designed to measure aggregate allowable costs, not service-specific costs. Despite its limitations, it is being used by CMS to establish DRG relative weights. As has been discussed, however, its use is likely to result in overpayment for some services and substantial underpayment for others. If cost report data are to be used to establish DRG relative weights, there is a need to modify it to measure the costs that are of interest. Two approaches for improving cost reports should be considered:

- Continued use of the existing cost reporting approach, but with improvements, and
- Design of a supplement to the cost report to be used to set cost-based weights.

Each of these approaches is discussed in the paragraphs that follow.

Improvements in the existing cost reporting approach. Although continued use of the existing cost reporting approach will not provide the most useful information for establishing DRG relative weights, steps can be taken to improve its accuracy and reduce distortions in costs used to set relative weights. Five steps should be considered.

- Prescribe a uniform chart of accounts that converts traditional cost objects to cost centers as part of the accounting process,
- Include all costs, not only allowable costs,
- Require greater uniformity in assigning costs to cost centers,
- Evaluate cost allocation bases and prescribe the use of the most appropriate bases, and
- Expand the number of ancillary cost centers to recognize differences in markups.

The Medicare program has not prescribed a uniform chart of accounts that all hospitals must use, although the account listings identified in Worksheet A have led to the development of a "de facto" chart of accounts that is used by many hospitals. All hospitals use charts of accounts that can support the account listing in Worksheet A. These accounts, however, are based on traditional accounting principles aimed at determining aggregate hospital costs. Rather than identify the costs of operating departments or cost centers, the existing trial balance identifies traditional cost objects, e.g., salaries, fringe benefits, supplies and utilities. The amounts listed in the trial balance for these cost objects represent total expenditures of each type that have been recorded over the course of a year.

Because traditional cost objects are used in hospital accounting systems, it is necessary to take the extra step of assigning each cost element to a cost center. A restructured chart of accounts that incorporates the use of cost centers rather than traditional cost objects would eliminate the extra step of assigning costs to cost centers as part of the cost reporting process. Assignments of cost would still need to be made, but they would be made as part of the ongoing accounting process rather than as an additional cost reporting step. Although there are no assurances that accuracy will be improved, focus on the assignment of costs as part of a hospital's accounting system is likely to lead to increased consistency in cost assignment decisions. Moreover, a change in the chart of accounts that emphasizes cost center accounting is a critical initial step in movement toward more sophisticated cost accounting.

In the cost report, non-allowable costs are removed from a hospital's trial balance to determine total allowable Medicare reimbursement, but these costs should be included in the calculation of DRG relative weights. When CMS uses cost report data to determine relative resource use among DRGs, removal of non-allowable costs distorts the measurement process. It is important for CMS to realize that when it uses cost data to establish DRG relative weights, it is unimportant whether Medicare reimbursement allows or does not allow a specific cost. CMS' objective should be to measure relative resource use across DRGs as accurately as possible and such measurement requires consideration of all costs.

Regardless of whether a new chart of accounts is introduced or existing charts of accounts continue to be used, there is a need to improve consistency in the assignment

of costs to cost centers. Regardless of how hospitals may be organized, they should be required to use similar approaches to assign costs. Standards are needed to determine how nursing and other professional salaries are distributed among cost centers when a staff member spends time working in more than one cost center. Similarly, standards are needed to be certain that there is consistency in how supply and pharmaceutical costs are assigned, i.e., to revenue centers or to Central Supply or Pharmacy. The Medicare program's past reluctance to promulgate standards were tied to the use of the cost report to determine aggregate reimbursable cost. If the cost report is to be used to calculate DRG relative weights, there is a need for increased consistency in the assignment of costs.

In addition to prescribing methods of assigning cost, there is a need to increase consistency in the principles used to allocate indirect costs to revenue centers. As previously discussed, selection of the most accurate allocation base for some revenue centers is straightforward. Utilities costs should be allocated based on square feet occupied by a cost center. Selection of appropriate allocation bases for other revenue centers is more difficult. For example, is it more accurate to allocate administrative costs based on the number of FTEs in a revenue center or on the total costs of the revenue center? It is less important to determine which approach is most accurate than it is to decide on which approach will be used by all hospitals to be certain that there is consistency in the data that are being combined to calculate DRG relative weights.

Increasing the number of revenue centers included in the cost report is the most important step that can be taken to improve the quality of cost report data used to calculate DRG relative weights. In its proposed regulations, CMS chose to combine revenue centers, which exacerbates distortions in cost measures. Some revenue centers have little variation in the markups applied to individual costs that are incurred, e.g., Routine Care, ICU and CCU. On the other hand, other revenue centers, including Diagnostic Radiology, Laboratory, Medical Supplies and Pharmacy, frequently include costs and charges for items for which markups may vary considerably. Since the cost to charge ratio is consistently applied to charges for all items in the revenue center to determine cost-based relative weights, it is highly likely that the costs used for several items will be substantially higher or lower than is appropriate. Although this issue is far less important in the determination of total reimbursable cost, it can be critical in determining the cost of a specific DRG. If the markup for all or most of the supplies used for a specific DRG are higher or lower than the average markup reflected in the cost to charge ratio, the relative weight that is calculated for that DRG may be significantly distorted. Analyses must be completed to determine how and why markups differ among items within a revenue center and additional revenue centers should be created to reflect the variances in markups that occur.

Each of the improvements in the existing cost reporting approach that have been identified will increase the accuracy of DRG relative weights as compared to the

approach that CMS described in the proposed regulations. Significantly greater changes in cost reporting are required, however, if CMS wants to substantially improve the accuracy of the DRG relative weight calculation process.

Design of a supplement to the cost report to be used to set cost-based weights. The purpose of the cost report is changing. The new objective for cost reports is to provide information to support an accurate calculation of the costs of resources required to provide the services described by each DRG. Calculation of allowable costs for Medicare reimbursement may still be perceived as needed by CMS, but must now be considered secondary to the need to calculate accurate DRG relative weights.

CMS needs a new cost report structure to accomplish the level of accuracy in cost measurement that is required. The structure should focus on the costs incurred to provide the services included in each DRG, as is currently available in cost accounting systems that many hospitals are now using. Although such systems were not in widespread use as recently as ten years ago, they are currently used by a large number of hospitals. If such systems are designated as required for cost reporting and small and rural hospitals are unable to purchase them, the Medicare program can pay these hospitals differently, as they do now. (A large number of rural hospitals are designated as critical access hospitals; these hospitals are paid using cost reimbursement).

CMS needs to take three steps to begin to design a supplement to the cost report that focuses on the calculation of DRG weights:

- Focus on what is being measured,
- Require the use of a cost accounting system that measures costs by DRG, and
- Establish minimum requirements for cost accounting systems.

The need to focus on the purpose of measuring costs has been the subject of much of this report. For its proposed move to the use of cost-based DRG weights, CMS has relied on a cost reporting structure designed for other purposes. A more appropriate structure can be developed to assure the fairness of the weights that are established.

As noted, many hospitals are using cost accounting systems that calculate DRG-specific costs. These systems have evolved to the point where their accuracy has been tested and they are regularly used to support management decisions. Although the systems vary to some extent, they are based on the measurement of standard costs, using approaches that are reasonably similar across hospitals. The DRG-specific cost data produced by these systems needs to be the foundation of a new cost report. Steps can be taken to design a report that requires DRG-specific costs to be reconciled to traditional accounting costs, but the use of cost accounting systems will eliminate the need for many of the concerns that have been identified for CMS' proposed method for calculating DRG weights.

CMS can identify requirements for acceptable cost accounting systems as part of the design of a new cost reporting format. Most hospitals will not need to modify their financial accounting systems nor will they be required to change the ways in which they present their financial statements. Instead, they will be able to report to CMS the same data that they use in management decision-making. Most importantly, far more accurate cost data will be available to calculate DRG relative weights.

APPENDICES

Appendix C - DRGs of Interest

DRG	Description
115	Perm Pacemkr Impl W/Ami/Hf/Shk
116	Oth Perm Cardiac Pacemaker Impla
118	Pacemaker Dev Replacement
515	Cardiac Defib Impl W/O Cath
535	Car Defib Impl w Cath AMI
536	Car Defib Implant wo AMI

Appendix B - Facilities Submitting Valid Data

Hospital	State
Christ Hospital	OH
Depaul Health Center	MO
Florida Hospital	FL
Good Samaritan Hospital	IL
Jewish Hospital	KY
Lahey Clinic Hospital	MA
Lancaster General Hospital	PA
Mease Countryside Hospital	FL
Mease Dunedin Hospital	FL
Morton Plant Hospital	FL
Morton Plant North Bay Hospital	FL
Orlando Regional Medical Center	FL
Providence Everett Medical Center	WA
Santa Rosa Memorial Hospital	CA
St. Anthony Hospital	OK
St. Francis Hospital	IL
St. Joseph's - Kirkwood	MO
St. Joseph's - St.Charles	MO
St. Mary's Hospital	WI
St. Mary's - Jefferson City	MO
St. Mary's - St. Louis	MO
Strong Memorial Hospital	NY

Appendix C.1 – Geographic Distribution of Cases

Region*	Participating Hospitals		Number of Cases	
	Count	%	Count	%
1	1	5%	479	6%
2	1	5%	599	8%
3	1	5%	887	12%
4	7	32%	2,982	39%
5	4	18%	1,295	17%
6	1	5%	346	5%
7	5	23%	495	7%
8	0	0%	0	0%
9	1	5%	189	3%
10	1	5%	280	4%
Totals	**22**	**100%**	**7,552**	**100%**

** State location of a hospital was mapped against CMS Regions*

Appendix 2 – Geographic Distribution of Cases By State

	No. of Hospitals	No. of Cases
Region 1		
Connecticut	0	0
Maine	0	0
Massachusetts	1	479
New Hampshire	0	0
Rhode Island	0	0
Vermont	0	0
Region 2		
New Jersey	0	0
New York	1	599
Puerto Rico	0	0
Region 3		
Delaware	0	0
District of Columbia	0	0
Maryland	0	0
Pennsylvania	1	887
Virginia	0	0
West Virginia	0	0
Region 4		
Alabama	0	0
Florida	6	2,468
Georgia	0	0
Kentucky	1	514
Mississippi	0	0
North Carolina	0	0
South Carolina	0	0
Tennessee	0	0
Region 5		
Illinois	2	489
Indiana	0	0
Michigan	0	0
Minnesota	0	0
Ohio	1	392
Wisconsin	1	414
Region 6		
Arkansas	0	0
Louisiana	0	0
New Mexico	0	0
Oklahoma	1	346
Texas	0	0
Region 7		
Iowa	0	0
Kansas	0	0
Missouri	5	495
Nebraska	0	0
Region 8	0	0
Colorado	0	0
Montana	0	0
North Dakota	0	0
South Dakota	0	0
Utah	0	0
Wyoming	0	0
Region 9		
Arizona	0	0
California	1	189
Hawaii	0	0
Nevada	0	0
Region 10		
Alaska	0	0
Idaho	0	0
Oregon	0	0
Washington	1	280

	No. of Hospitals	No. of Cases
Totals	22	7,552

** State location of a hospital was mapped against CMS Regions*

ATTACHMENT 7

Table on DRG and CS-DRG Mismatches

Examples of DRG Adjustments Adopted Through Notice and Comment Rulemaking That Would Be Negated If CMS Implements APR-DRGs in FY 2007

CURRENT CMS DRG	Date Originally Adopted by CMS Through Rulemaking	Rationale for Change	CMS Consolidated Severity- Adjusted (CS) DRG Mapping	Impact Of Severity Adjustment*
557 & 558, Drug-Eluting Stent with/without Major Cardiovascular Diagnosis	FY 2003 (original), modified in FY 2006	CMS: "We recognize that the resources surrounding bare metal stents and drug-eluting stents differ appreciably and will continue to keep these cases separate..." Federal Register, Vol. 70, 47294, August 12, 2005	CSA-DRGs 237-242 Percutaneous Caridovascular Procedures **[all coronary angioplasty is grouped here, regardless of whether a stent is inserted]**	DRG 557: -23% DRG 558: -33%
559, Acute Ischemic Stroke with Use of a Thrombolytic Agent	FY 2006	CMS: "We agree...that there is an increased cost in caring for these [stroke tPA] patients including increased use of the intensive care unit, more diagnostic imaging studies, and laboratory and pharmacy resources. We also agree that—(1) the data indicate that patients receiving thrombolytic therapy have increased severity; and (2) reperfusion therapy is a good means to segregate these patients into a separate DRG." Federal Register, Vol. 70, 47288. August 12, 2005.	CSA-DRGs 56-58 CVA & Precerbral Occlusion W Infarction. **(Revert to claissifying tPA back with all other stroke cases, undoing what they did just last year.)**	-35%
551, Permanent Cardiac Pacemaker Implant with Major CV Diagnosis or AICD Lead or Generator	FY 2006	CMS: "Using the MCV list, we tested our assumption that these conditions described a more severe set of cardiovascular surgery patients. We grouped all the cardiovascular surgery patients within MDC 5 based on the presence or absence of an MCV condition. We found that this split was predictive of significantly increased resource use for nine surgical cardiovascular DRGs." Federal Register, Vol. 70, 47474, August 12, 2005	CSA-DRGs 228-233 Permanent Cardiac Pacemaker Implant With & W/O AMI, Heart Failure or Shock **(Reverts back to classification based on presence or absence of heart failure, AMI, or shock, rather than Major Cardiovascular Diagnosis)**	-17%

545, Revision of Hip or Knee Replacement	FY 2006	CMS: "For the FY 2006 IPPS proposed rule, we examined data in the FY 2004 MedPAR file on the current hip replacement procedures (codes 81.51, 81.52, 81.53) as well as the replacements and revisions of knee replacement procedures (codes 81.54 and 81.55) in DRG 209. We found that revisions were significantly more resource intensive than the original hip and knee replacements." Federal Register, Vol. 70, 47305, August 12, 2005.	CSA-DRGs 414-419 Hip Joint Replacement (414-416) & Knee Joint Replacement (417-419) **(Would undo last year's change to recognize the increased resources for revisions.)**	-10%
496, Combined Anterior/Posterior Spinal Fusion	FY 1998	CMS: "In view of the volume of cases involved and the clear differences in resource use, we concluded that it would be appropriate to create additional DRGs to separate spinal fusion cases from the other back and neck procedures... The average charges and lengths of stay for the cases involving both anterior and posterior spinal fusion were markedly greater than for the other spinal fusion cases... [W]e concluded that the magnitude of the differences in both average charges and lengths of stay warranted a further subdivision of the spinal fusion cases." Federal Register, Vol. 62, 45976, August 29, 1997.	CSA-DRGs 413, 421-425, 461-463 **(Combined anterior/posterior spinal fusions appear simply to be regrouped with all other spinal fusions, ignoring the greater resource intensity and LOS associated with these cases and reversing the policy from the FY 1998 final rule.)**	-38%
551, Permanent Cardiac Pacemaker Impl w/ Maj CV DX or AICD Lead or Generator	FY1997, Moved from the lower-paying DRG 116 (Pacemaker System w/o AMI, HF, Shock) to higher-paying DRG 115 (Pacemaker System w/o AMI, HF, Shock)	CMS: "Because the average charge of AICD cases continued to be much higher than the average charge for all other DRG 116 cases we propose to move them to DRG 115" Federal Reg. Vol. 62, 45974, August 29, 1997.	CSA-DRGs 243-245. Cardiac Pacemaker and Defibrillator Device Replacements – Defibrillator replacements are now grouped with pacemaker replacements instead of the higher paying pacemaker system implant DRG.	-49% (assuming SOI 1 for replacements)

*Weighted average reduction.

3

ATTACHMENT 8

Analysis of FY 2004 Payment to Cost Ratios for ICD and Pacemaker DRGs

DRG	MDC	DRG Description	DRG Type	2004 Relative Weight	Case Count	Avg. Length of Stay	Avg. Total Allowed Amount (DRG Amt + Outlier Amt)	Avg. Total Charges	[illegible]
115	05	PRM CARD PACEM IMPL W AMI/HR/SHOCK OR AICD LEAD OR GNRTF	SURG	3.5465	21,975	6.8	20,521	64,599	[illegible]
116	05	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT	SURG	2.3590	117,503	4.3	13,141	40,585	[illegible]
118	05	CARDIAC PACEMAKER DEVICE REPLACEMENT	SURG	1.6089	7,586	3.1	9,334	29,970	[illegible]
515	05	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	SURG	5.3366	27,095	4.3	32,059	98,063	[illegible]
535	05	CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK	SURG	8.1560	12,939	8.2	48,559	133,223	[illegible]
536	05	CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK	SURG	6.2775	19,468	5.4	37,476	110,323	[illegible]

DRG	Avg. Total Routine Charges	Total Routine Costs	Avg. Total Departmental Charges	Avg. Intensive Care Charges	Avg. Intensive Care Costs	Avg. Pharmacy Charges	Pharmacy Costs	Avg. Med/Surg Supply Charges	Avg. Med/Surg Supply Costs	Avg. Operating Room Charges	Avg. Operating Room Costs	Avg. Laboratory Charges	Avg. Laboratory Costs
115	10,850	7,340	53,749	7,389	4,573	4,109	1,076	29,931	7,598	5,879	1,865	3,476	726
116	6,398	4,328	34,187	4,172	2,587	1,953	511	18,846	4,784	4,784	1,518	1,965	411
118	4,841	3,275	25,129	2,748	1,704	1,329	348	14,326	3,637	4,240	1,345	1,451	303
515	6,605	4,468	91,458	4,522	2,804	3,113	815	67,030	17,016	9,176	2,911	2,190	457
535	14,678	9,930	118,545	10,019	6,211	6,857	1,795	74,257	18,850	10,281	3,261	4,718	986
536	9,249	6,257	101,074	6,146	3,810	3,823	1,001	66,318	16,835	9,439	2,994	2,702	565

DRG	Avg. Radiology Charges	Avg. Radiology costs	Avg. Other Charges	Avg. Other Costs
115	1,790	367	1,174	333
116	1,498	307	970	275
118	715	146	4,561	1,293
515	1,456	298	13,148	3,727
535	2,286	468	20,408	5,786
536	1,752	359	10,893	3,088

ATTACHMENT 9

Materials on Medtronic Product-Specific DRG & Code Issues in Proposed Rule

DRGs: Neurostimulators

Kinetra® is an implantable dual array neurostimulator pulse generator used in deep brain stimulation (DBS) for the treatment of Parkinson's disease. This neurostimulator was approved for a new technology add-on payment beginning in 2005. The add-on payment will end at the close of the current fiscal year, but a request was made by Medtronic to reassign the therapy from DRGs 001-002 to DRG 543, a more clinically and cost coherent DRG. The request for reassignment was made out of concern that Kinetra® will be underpaid with the conclusion of the new technology add-on payment. To accommodate this recommendation, procedure codes 02.93 and 86.95 would be reassigned to DRG 543 and the title for DRG 543 would be revised to "Craniotomy with Implantation of Major Device or Acute Complex CNS Principal Diagnosis."

In the Proposed Rule, CMS rejects the request to reassign full-system Kinetra® implants to DRG 543 (Craniotomy with Implant of Chemo Agent or Acute Complex CNS Principal Diagnosis). Instead, CMS proposes to continue to pay for these procedures under DRG 001(Craniotomy Age>17 with CC) or DRG 002 (Craniotomy Age>17 without CC).

The Proposed Rule provides CMS' analysis of the FY 2005 MedPAR file for full-system DBS implants assigned to DRG 001 or DRG 002 (as identified by cases with procedure codes 02.93 and 86.95). This analysis demonstrates that the average charges for the full-system dual array neurostimulator pulse generator cases are approximately $18,000 and $27,000 higher than the average charges for DRGs 001 and 002 respectively. CMS also acknowledges that the average charges for theses cases in DRG 001 are comparable to those of DRG 543. CMS goes on to state that charges for these cases in DRG 002 are less than those in DRG 543 by nearly $12,000. Even so, the charges are more consistent with resource consumption in DRG 543 than in DRG 002 where they exceed the average by $27,000.

As demonstrated in Table 1 below, average charges for full-system cases in DRG 001 are 32% higher than all other cases in DRG 001, and 81% higher than all other cases in DRG 002.

Table 1

DRG	Description	Number of Cases[1]	Average Charges[1]	Difference[2]	Percent Difference[2]
001	Cases with 02.93 + 86.95 (Kinetra®)	51	$73,020	$17,526	32%
	All Cases	23,037	$55,494		
002	Cases with 02.93 + 86.95 (Kinetra®)	146	$59,414	$26,623	81%
	All Cases	9,707	$32,791		

1. Data from Federal Register/Vol. 71, No.79/Tuesday, April 25, 2006/Proposed Rules, page 24031
2. Difference between Kinetra® cases and all cases in DRG

Per CMS's analysis and findings, it is apparent that the resources utilized in full-system Kinetra implants in both DRG 001 and 002 are not consistent with resources consumed by all other cases in these DRGs.

The charges and number of cases for full-system DBS implants remain consistent with charges for the Gliadel wafer, which was reassigned to DRG 543 in 2005. Using the FY 2004 MedPAR data file, a total of 127 cases constituted the Gliadel rationale for assignment to a new DRG - 80 cases in DRG 001 and 47 in DRG 002. The average standardized charge for DRG 543 was $66,543 in the FY 2004 MedPAR file. The charges for the Gliadel cases were $61,866 (DRG 001) and $47,189 (DRG 002) resulting in a case weighted average of $56,434. The Gliadel weighted average charges were approximately $10,000 less than the average for DRG 543.

As reflected in the FY 2005 MedPAR data file, there are 51 full-system DBS cases in DRG 001 and 146 in DRG 002 for a total of 197. The DBS cases have average charges of $73,020 in DRG 001 and $59,414 in DRG 002. This results in a weighted average charge of $62,936, only $8,200 less than the average charge of $71,138 for DRG 543. Both the number of cases and the case-weighted charges are higher for the full-system DBS cases than what was required for approval of the Gliadel reclassification.

The CMS data clearly suggests that full-system DBS cases will be underpaid in both DRG 001 and 002. However, CMS suggests that the charge markup may explain the higher charges but lower average length of stay, citing a national average CCR for medical equipment and supplies of approximately 34 percent. However, CMS does not provide any actual evidence that markup -- and not the cost of the device -- accounts for the charges associated with full-system DBS cases. We disagree with CMS' statements that mark-ups associated with the Kinetra device are excessive and overstate the total charges of the implant procedure. We are submitting information during the comment period that we believe conclusively finds that hospital charge mark-ups for implantable devices are in fact significantly lower than for other, lower cost supplies and equipment. (Based on this finding, we are submitting a proposal that would make adjustments to correct for the impact of charge compression in the setting of cost-based weights.)

Although the 2005 MedPAR data captures full-system DBS cases, there is a significant dilutional effect due to the lower volume of these procedures compared to the remainder of services in these DRGs. DBS is a demanding specialty procedure and is performed only at selected hospitals. Data dilution will have a significant impact on these hospitals and may lead to renewed issues with access for Medicare beneficiaries.

We therefore believe that, if anything, the total charges found in MedPAR associated with Kinetra implant procedures may be <u>understated</u> relative to other procedures in DRGs 543, 001, and 002, and that the reassignment of the technology to DRG 543 is fully warranted. Given that we are recommending deferral of the implementation of the consolidated severity DRGs until at least FY 2008, we believe the CS-DRGs should not be a factor in CMS's decision to make DRG reassignments this year. **We strongly encourage CMS to reclassify the Kinetra procedure – determined by CMS to be a significant clinical improvement over previous therapy for Parkinson's disease – to the more appropriate DRG 543.**

DRGs: Cardiac Resynchronization Therapy, Defibrillators (CRT-D)

We agree with the proposal to add code 37.74 (Insertion or Replacement of Epicardial Lead [Electrode] into Epicardium) to the DRG logic for Implantable Cardioverter Defibrillator (ICDs) so that all types of defibrillator devices and lead combinations would appropriately map to the following DRGs:

- DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheter);
- DRG 535 (Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock); and
- DRG 536 (Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock).

This change will bring the DRGs into alignment with the 2005 change in coding advice to assign code 37.74 in conjunction with implantation of CRT-D defibrillators.

Incidentally, the code description listed in the Proposed Rule incorrectly describes 37.74 as "Insertion or replacement of epicardial lead [electrode] into *atrium*". The correct description for 37.74 is "Insertion or replacement of epicardial lead [electrode] into *epicardium*".

Proposed Classifications of ICD-9-CM Procedure Codes

Table 6B.—New Procedure Codes

Medtronic would like to acknowledge the following new coding:

00.56 - *Insertion or replacement of implantable pressure sensor (lead) for intracardiac hemodynamic monitoring.*

00.57 - *Implantation or replacement of subcutaneous device for intracardiac hemodynamic monitoring.*

Medtronic supports the DRG assignments for the above new codes. We believe that after a sufficient time has elapsed for these to be fully reflected in the claims system, CMS should again re-evaluate the data to verify assignment.

37.20 - *Noninvasive programmed electrical stimulation [NIPS]*

37.26 – *Catheter based invasive electrophysiologic testing* (Table 6F.—Revised Procedure Code Titles)

Prior to the introduction of procedure code 37.20, procedure code 37.26 was inclusive of **both** a catheter based EP study and a non-invasive programmed electrical stimulation (two very distinct procedures with different resource requirements).

In FY 2006 CMS determined that an EP study no longer qualified as a cardiac catheterization in accordance with the defibrillator DRG definitions. This was in part due to the combination of procedures historically reflected in 37.26. We believe the coding changes, which distinguish a catheter based EP study from a non-invasive programmed electrical stimulation, are a step in the right direction to delineate these procedures for data purposes. We believe the coding changes, which distinguish an invasive catheter based EP study from a non-invasive programmed electrical stimulation, are a step in the right direction to delineate these procedures for data purposes. **Medtronic urges CMS to consider 37.26 as a qualifying cardiac catheter procedure.**

Medtronic appreciates the opportunity to work with the ICD-9-CM Coordination and Maintenance staff who are interested in correct coding and desire to understand and present the most appropriate coding recommendations.

176

ADEA
American Dental Education Association

The Mission of the American Dental Education Association is to lead individuals and institutions of the dental education community to address contemporary issues influencing education, research, and the delivery of oral health care for the improvement of the health of the public.

June 12, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201
Attention: CMS-1488-P

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates -- CMS -1488-P

Dear Administrator McClellan:

The American Dental Education Association (ADEA) appreciates the opportunity to comment on the proposed rule for changes to hospital inpatient prospective payment systems for fiscal year 2007, as published in the April 25, 2005 *Federal Register*. Specifically, we will comment on proposed changes to graduate medical education (GME) policies which will have a very deleterious impact on residency training.

ADEA is the national organization that speaks for dental education. It is dedicated to serving the needs of all 56 U.S. dental schools, 731 U.S. dental residency programs, 266 dental hygiene programs, 259 dental assisting programs, and 25 dental laboratory technology programs, as well as the 11,332 full- and part-time dental school faculty, more than 5,060 dental residents (both hospital- and school-based) and the nation's 36,286 dental and allied dental students.

Comments Regarding Section IV(F)(5) -- Resident Time Spent in Nonpatient Care Activities as Part of Approved Residency Programs (Sections 413.9 and 413.78(a))

We are gravely concerned with the entire discussion in this section of the proposed rule regarding didactic activities that are a seminal component of every residency program. CMS's view regarding the treatment of this issue over the years, in our opinion, bears little resemblance to the actual language in the Medicare statute, regulations, manual and CMS's own correspondence.

1400 K Street, NW • Suite 1100 • Washington, DC 20005 • Phone: 202.289.7201 • Fax: 202.289.7204 • Internet: www.ADEA.org

We agree with CMS that only time spent by residents training in a nonprovider setting performing "activities relating to patient care" may be counted towards direct graduate medical education (D-GME) and indirect medical education (IME) funding. However, in using this language, it is very clear that Congress intended for more than just direct patient care to be included. Indeed, as described below, CMS regulations, manual provisions and correspondence also support this conclusion.

The Medicare Statute

In a very misleading fashion in the proposed rule, CMS does not quote the entire section of the relevant portion of the Medicare statute, which reads in full:

> "Counting Time Spent in Outpatient Settings. Such rules shall provide that only time spent in activities relating to patient care shall be counted and that all the time so spent by a resident under an approved medical residency training program shall be counted toward the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training in that setting." (Emphasis added). Section 1886(h)(4)(E) of the Social Security Act.

Congress and CMS itself know what language describes care directly provided to individual patients. That term is "direct patient care". Congress uses the term "direct patient care" in 42 USC Section 1395m regarding special payment rules for compensation provided to a referring physician for direct patient care services, and again in Section 1395nn, in distinguishing administrative services from direct patient care.

Significantly, however, the statutory language regarding this GME issue does not use the term "direct patient care," but rather employs the much broader language of "activities relating to patient care." Further, the law states that "all the time so spent by a resident under an approved medical residency training program shall be counted . . . without regard to the setting in which the activities are performed." (Emphasis added.)

In addition to Congress using the phrase "direct patient care" when that is what it means, CMS uses the phrase "direct patient care" frequently. Examples include:

- ✓ 42 CFR Sections 460.71, 460.62, 418.70, 418.100, 413.106;
- ✓ Proposed rule for physician services for 2005 (69 Fed. Reg. 150 at 47491);
- ✓ Interim final rule for Programs of All-inclusive Care for the Elderly (PACE) (67 Fed. Reg. 190 at 61499);
- ✓ Medicare Provider Reimbursement Manual, Transmittal 13, October 2003;
- ✓ Medicare Benefit Policy Manual, Chapter 11, Section 80.2, Physicians' Services - Outpatient Maintenance Dialysis;
- ✓ Medicare Benefit Policy Manual, Chapter 9, Coverage of Hospice Services;
- ✓ Medicare Claims Processing Manual, Chapter 3, Section 141.1.3Q, Inpatient Hospital Billing; and
- ✓ State Medicaid Manual, Chapter 4, Section 4307 (Payment for Physician Services Under Hospice).

Medicare regulations also define "direct medical and surgical services" of physicians in a teaching setting as "services to individual beneficiaries that are either personally furnished by a physician or furnished by a resident under the supervision of a physician in a teaching hospital . . . ." 42 CFR Section 415.152.

In all these situations where Congress or CMS used the phrase "direct patient care" or "direct medical and surgical services," it meant care provided directly to specific patients. To describe hands on care provided directly to individual patients, neither Congress nor CMS has used the phrase "activities relating to patient care."

Medicare Regulations and Provider Manual

The Medicare regulations relating to training in a nonprovider setting state:

> "For portions of cost reporting periods occurring on or after January 1, 1999, the time residents spend in nonprovider settings such as freestanding clinics, nursing homes, and physician offices in connection with approved programs may be included in determining the number of FTE residents in the calculation of a hospital's resident count if the following conditions are met: (i) The resident spends his or her time in patient care activities . . . ." (Emphasis added). 42 CFR 413.78(a).

Consistent with the statutory language, the reference in the regulations is to patient care "activities" and not to direct patient care.

CMS states that the regulations at 42 CFR Section 413.9 support its position that didactic time is not a patient care activity. Actually, these regulations fully support the interpretation that the costs of didactic training are in fact related to patient care.

Section 413.9 requires that the costs that a hospital places on its cost report be related to patient care to be reimbursed.

> "Costs related to patient care . . . . Necessary and proper costs are costs that are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities." (Emphasis added). 42 CFR 413.9

The Provider Manual expands on this language by stating that all costs of an approved Interns and Resident training program are allowable as "Costs Related to Patient Care". PRM Section 2148.

In addition, "Costs Related to Patient Care" also is defined in the Provider Manual as "all necessary and proper costs which are appropriate and helpful in maintaining the operation of patient care facilities and activities." PRM Section 2102.2

Moreover, the Provider Manual also lists examples of "Costs Not Related to Patient Care". (Emphasis added). The Provider Manual states that costs not related to patient care are the cost of meals sold to visitors, cost of drugs sold to other than patients, cost of operating a gift shop, cost of entertainment, cost of educational expenses for spouses or other dependents of providers of services, etc. PRM Section 2102.

Thus, in listing the costs that are not related to patient care, the Provider Manual specifically mentions the education expenses for spouses and other dependents of providers of services. Notably, the Provider Manual does not mention the educational expenses of providers of services, such as residents, themselves. Therefore, the educational expenses

of these providers of services must be related to patient care. That is the only reasonable interpretation.

Further, in a recent Q and A that CMS issued on April 8, 2005, entitled "Medicare Policy Clarifications on Graduate Medical Education Payments for Residents Training in Non-Hospital Settings," CMS defines in its answer to Question #5 what are the teaching supervisory costs that a hospital must incur with respect to training occurring in a nonhospital site in order to quality for D-GME and IME funding. CMS states that the teaching physician costs that the hospital must incur do not include billable direct patient care time, but rather include time spent on non-billable GME teaching activities, "such as general clinical didactic training or assessing the resident's performance." (See Answer #5, at Attachment #1.)

Therefore, according to this CMS instruction, the hospital must incur the cost of the faculty teaching the didactic seminars, but then, according to this proposed rule, the hospital cannot count the time the residents spend in these seminars. Such a result would be absurd policy.

CMS Correspondence

Perhaps most significant, the CMS official who directly oversees GME policy issues, addressed the very question at issue here in 1999. In response to correspondence asking how CMS interprets the phrase "patient care activities" with respect to training occurring in nonprovider settings, Tzvi Hefter, Director, CMS Division of Acute Care, in a letter dated September 24, 1999, attached, responded:

> "HCFA interprets the phrase 'patient care activities' broadly to include any patient care oriented activities that are part of the residency program. As you stated in your letter, this can include . . . scholarly activities such as educational seminars, classroom lectures, research conferences, patient care related research as part of the residency program and presentations of papers and research results to fellow residents, medical students, and faculty. Therefore, as long as the residents are primarily involved in patient care oriented activities and other program requirements are met, a hospital may include other educational activities as part of the entire time spent by residents in non-hospital settings and include this time in its FTE count and GME/IME payment calculations." (Emphasis added.) (See Attachment #2).

We do not believe the CMS letter could have been more clear or to the point. Further, as described above, this CMS interpretation of "patient care activities" is supported by the language of the Medicare statute and regulations, neither of which refer to "direct patient care," but rather mention "activities relating to patient care."

CMS's main argument in the proposed rule is that the plain meaning of "patient care activities" clearly means direct patient care. If the meaning was not plain to the CMS Director overseeing GME issues himself, how then could it have been plain to hospitals and medical and dental schools?

As CMS is well aware, and contrary to its implication in the proposed rule, this 1999 CMS correspondence was distributed widely to many hospitals and universities. Indeed, ADEA explained this to CMS officials in a meeting in April of 2004. Many hospitals and medical

and dental schools have relied upon the CMS letter's unequivocal language, which states that hospitals could include resident didactic time in a nonhospital setting in calculating FTEs for D-GME and IME.

Federal District Court Opinion in *Riverside*

In a case involving Riverside Methodist Hospital in Ohio, the fiscal intermediary denied IME payments to the hospital for time the family practice residents were in journal club, practice management seminars, ob/gyn seminars, and psychiatric seminars. The basis for the intermediary's denial was that this time was not related to "hands-on patient care." All of these activities, however, were required components of the family practice residency program under the ACGME standards.

The hospital appealed the fiscal intermediary's denial to the Provider Review Reimbursement Board (PRRB), and the PRRB sided with the hospital, concluding that this didactic time should be counted. The CMS Administrator reversed the PRRB's decision in November of 2001, however, and the hospital appealed to Federal District Court.

A Federal District Court in 2003 reversed the CMS Administrator's position that didactic time couldn't be counted for IME payments at least for training occurring in a hospital setting, in Riverside Methodist Hospital v. Thompson, 2003 U.S. Dist Lexis 15163 (S.D. Ohio, July 31, 2003). In Riverside, the Court held that in the hospital setting there was no requirement that a resident's time be counted only if it involved patient care.

The Court did not need to resolve or decide the question of whether this didactic time was related to patient care. However, the Court did take note of the issue in footnote 11, stating:

> "It could be very difficult to define exactly what is included in the Secretary's phrase 'patient care costs.' For example, if a resident suspects that a patient has a mental disorder, and does some research in order to better understand the patient's condition and treatment, is this time spent for 'patient care'? If the same resident, for the same purpose, attends a psychiatric seminar, is this time spent for 'patient care'?"

Didactic Activities Are Relating To Patient Care

Lastly, the didactic activities that are included in all ACGME and CODA accredited residency programs are activities relating to patient care as the Medicare statute and regulations require. In conferences and seminars, the residents are encouraged to discuss how the material relates to patients whom they are treating. The journal clubs, literature reviews, case presentation, laboratory techniques are related to patients who are being treated. Even seminars on communication skills are related to patient care, as communication with patients, family, and other professionals is discussed in the context of how to care for patients presently.

Conclusion

As described above, the Medicare statute and regulations do require that residents be involved in activities relating to patient care for the time to be counted towards D-GME and IME in a nonhospital setting. However, the Medicare statute, regulations, manuals, and

CMS's own correspondence make very clear that "activities relating to patient care" include more than just direct patient care and that didactic time that is part of an ACGME- or CODA-accredited program is an activity relating to patient care. Therefore, this didactic time meets the statutory and regulatory definition of activities related to patient care and should be counted for both D-GME and IME purposes.

* * * *

We look forward to working with CMS staff to resolve this critical issue. If there are any questions concerning these comments, please contact Jack Bresch, Associate Executive Director and Director of the Center for Public Policy and Advocacy, American Dental Education Association, at 202/667-9433, Ext. 120.

Respectfully submitted by,

Kenneth L. Kalkwarf, D.D.S.
President

Richard W. Valachovic, D.M.D., M.P.H.
Executive Director

Attachment 176

ATTACHMENT 1

04/08/2005

MEDICARE POLICY CLARIFICATIONS ON GRADUATE MEDICALEDUCATION PAYMENTS FOR RESIDENTS TRAINING IN NON-HOSPITAL SETTINGS

Question 1) How does Medicare support Graduate Medical Education (GME) programs?

Answer 1) Medicare makes both direct GME and indirect GME (IME) payments to hospitals that train residents in approved medical residency training programs. The calculation of both direct GME and IME payments is affected by the number of full-time equivalent (FTE) residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. The Medicare statute provides for direct GME payments to hospitals to cover Medicare's share of the **hospital's** direct costs of the residency training taking place at the hospital. The direct GME payment is based on a hospital-specific per resident payment amount that is based on the **hospital's** direct graduate medical education program costs (including teaching physician and resident salaries) incurred in a base year. IME payments to a hospital are paid under the Inpatient Prospective Payment System (IPPS) as a percentage add-on for each Medicare patient discharged from the hospital. IME payments are designed to cover Medicare's share of the higher indirect costs of providing patient care at teaching hospitals relative to non-teaching hospitals. The higher costs are primarily due to increased or inefficient testing of patients by residents and the relatively increased level of patient acuity at teaching hospitals.

Question 2) Does Medicare make both direct GME and IME payments to hospitals for training residents at nonhospital sites?

Answer 2) Prior to October 1, 1997, hospitals could receive only direct GME payments for the time that residents train in nonhospital settings. However, Congress recognized the importance of moving more resident training out of the hospital setting and into settings that more closely reflect the settings where most physicians will practice. Accordingly, beginning with discharges occurring on or after October 1, 1997, the Balanced Budget Act of 1997 (BBA), amended the Medicare statute to allow hospitals to count residents in nonhospital sites for IME payment purposes as well. In making this change Congress intended to encourage hospitals to rotate more residents to nonhospital sites. In implementing this provision, CMS acknowledges the value of training more residents in nonhospital sites and it is our intent to make sure our rules encourage and facilitate this kind of activity.

However, since the per resident direct GME payment is based on all of the costs incurred by the hospital in training residents during a base year (including teaching physician costs), we believe Congress intended to permit hospitals to count time spent by residents training in nonhospital sites for purposes of IME and direct GME payments only if the hospital is actually incurring "all or substantially all the costs" of the residents training at

the nonhospital site. For this reason, our current regulations require a hospital to incur the residents' salaries and fringe benefits, travel and lodging costs where applicable and the cost of teaching physicians' salaries and fringe benefits attributable to supervision of resident training in the nonhospital setting.

Question 3) Are there situations where it's ok for a physician to volunteer his/her time to supervise residents in a nonhospital site?

Answer 3) Under section 1886(d)(5)(B)(iv) of the Social Security Act for IME, and section 1886(h)(4)(E) for direct GME, the time residents spend training in nonhospital settings in connection with approved programs may be included in determining the hospital's number of full time equivalent (FTE) residents, if, in addition to other requirements, the hospital incurs "all or substantially all" of the costs for the training program in the nonhospital setting. Accordingly, the relevant question is *not* whether volunteerism is permissible, but whether *there is a cost* to the nonhospital site for supervising the resident training. If there is a cost, the hospital must reimburse the nonhospital site for those costs. If there are no costs, then no payment for supervisory physician time is required. Typically, there is a cost for teaching physician time if, for example, the physician receives a predetermined compensation amount for his/her time at the nonhospital site that does not vary with the number of patients he/she treats. In contrast, there is typically no cost for teaching physician time if the physician's compensation at the nonhospital site is based solely and directly on the number of patients treated and for which he/she bills. The most obvious example of this situation would be a solo practitioner that serves as a nonhospital training site. With respect to compensation for teaching physicians, the hospital is required to compensate the nonhospital site for the costs of the teaching physician's activities provided in connection with an approved residency program <u>other</u> than the supervision of residents while furnishing billable patient care services. That is, only the costs associated with teaching time spent on activities within the scope of the GME program, but <u>not</u> in billable patient care activities, would be considered direct GME costs that would need to be incurred by the hospital.

Question 4) In the context of GME training in nonhospital sites, what is the difference between a "solo practitioner" and a "member of a group practice"?

Answer 4) A solo practitioner works in his/her own private office and a member of a group practice is typically one of several physicians employed at a particular nonhospital site. The solo practitioner's compensation is based solely and directly on number of patients treated and for which he/she bills. When the solo practitioner is not treating patients, he/she is not receiving payment for any other duties at the nonhospital site. In this instance, there is <u>no</u> cost to the nonhospital site for the teaching physician's time. In the case of the group practice or clinic setting, however, the physician often receives a predetermined payment amount, such as a salary, for his/her work at the nonhospital site. This predetermined payment amount reflects *all* of his/her responsibilities at the nonhospital site, including treating patients, training residents, and other administrative activities (as applicable), and he receives that predetermined payment from the nonhospital site regardless of how many patients he/she actually treats. The

predetermined amount implicitly compensates the physician for supervising residents. A portion of this implicit compensation is the *cost* attributable to teaching activities, and the hospital must pay the nonhospital site this amount.

Question 5) How do we determine the amount of teaching physician costs that the hospital must pay the nonhospital site?

Answer 5) Determination of the teaching physician costs to the nonhospital site is dependent upon the teaching physician's salary and the percentage of time he/she devotes to activities related to non-billable GME activities at the nonhospital site. Assume, for example, that a resident spends 30 hours per week training at the nonhospital site and the teaching physician works 40 hours per week at the nonhospital site. Also assume that 20 out of the resident's 30 hours are spent in billable patient care activities supervised by the teaching physician, leaving 10 hours of the time the teaching physician spends with the resident in non-billable GME teaching activities, such as general clinical didactic training or assessing the resident's performance. Accordingly, 25 percent (10/40) of the teaching physician's time is spent with the resident in non-billable GME activities. Additionally, the teaching physician may take some time beyond the 30 hours spent with the resident to perform some administrative tasks related to the program, such as completing resident evaluation forms. Again, for illustrative purposes, assume the teaching physician spends one hour out of the 40-hour workweek, or 2.5 percent of his/her time, completing evaluation forms. Therefore, in this example, the teaching physician spends 27.5 percent (25 percent plus 2.5 percent) of his/her time in non-billable GME activities. If the teaching physician receives a salary of $100,000 per year, then 27.5 percent, or $27,500 is the direct GME cost of the physician's teaching activities in the nonhospital site for a whole year. In this example, the hospital would need to pay $27,500 to the nonhospital site in order to count the FTE resident time spent in the nonhospital site for direct GME and IME payment purposes. (If residents are not trained at the nonhospital site throughout the whole year, then $27,500 would be prorated based on the number of weeks that residents train at the nonhospital site).

Question 6) Should the written agreement be with the teaching physician or with the nonhospital site where the physician works?

Answer 6) If the physician is self-employed (e.g., a solo practitioner in his/her own private office), then the physician and nonhospital site are one and the same, and the agreement would be with the physician. However, if the physician is an employee, or must report to another official(s) at the nonhospital site, then the written agreement must be between the hospital and an authorized representative of the nonhospital site.

Question 7) What if the physicians supervising the resident training at the nonhospital sites are employees of the hospital?

Answer 7) If the teaching physicians are employees of the hospital, and the physicians do not receive any additional compensation from the nonhospital site, no additional payment from the hospital is needed since the salaries paid by the hospital to the physicians cover

teaching costs inside and outside of the hospital. In such a case, the written agreements should indicate that the teaching physicians are on staff at the hospital, and the hospital is already incurring the teaching physician costs for training time in nonhospital settings (unless, after October 1, 2004, the hospital opts to forego a written agreement and, instead, documents that it pays the nonhospital site for the teaching physician costs concurrently with the training at that site in accordance with 42 CFR §413.78(e)).

Question 8) Must the hospital incur the teaching physician costs and have a written agreement with the nonhospital site if a) the nonhospital site is owned by the hospital, or b) the nonhospital site is owned by the same organization that owns the hospital?

Answer 8) In either scenario, the hospital must incur the teaching physician costs, and there must be a written agreement in place before the time the residents begin training in the nonhospital site (unless 42 CFR §413.78(e) applies, in which case a written agreement is not required). The hospital would need to demonstrate, under either ownership scenario, that it is paying all or substantially all of the costs of the training program by actually paying the nonhospital site through the hospital's accounts payable system. (If the hospital and nonhospital site share a single accounting system, the hospital could demonstrate payment of the nonhospital site training program costs using journal entries that expense these costs in the hospital's GME cost center and credit the nonhospital site.)

Question 9) What if the teaching physician is on the staff of a medical school and supervises residents in the hospital and in clinics owned by the medical school?

Answer 9) In this case, (unless the hospital opts to pay for the training program costs concurrently under 42 CFR §413.78(e)), rather than having a written agreement with each clinic, it would be appropriate for the hospital to have a written agreement with the medical school, since the medical school owns the clinics. If the residents are training in various medical school clinics, the hospital must have written agreement(s) reflecting the compensation arrangements for each clinic.

Following are examples of situations where there is no teaching physician cost associated with resident training in nonhospital sites, and, therefore, the hospital would not be required to pay the nonhospital site for teaching physician time in order to count the residents for direct GME and IME purposes:

a) A physician trains residents in his private practice. He is a solo practitioner; he does not share the office with other physicians. His compensation is based solely and directly on the number of patients treated and for which he bills.
b) A physician that supervises residents in her private practice shares office space with two other physicians. The three physicians share overhead expenses, such as electricity and rent, but otherwise, there is no sharing of revenues from patient care activities, and the physicians are not compensated according to some predetermined arrangement. Despite sharing office space, the physician that supervises the residents essentially operates as an independent practitioner,

receiving her compensation solely and directly from the number of patients she treats and for which she bills.

c) A resident goes along with a *solo practitioner* to see the physician's patients in a freestanding nursing home (not a Medicare-certified skilled nursing facility). The physician does not receive any payment from the nursing home, and bills independently for the patient care services he provides.

Following are examples of situations where there could be a teaching physician cost associated with resident training in nonhospital sites since, in each instance, the physician receives a predetermined compensation amount regardless of the number of patients he/she treats. In these instances, the hospital is required to identify and pay for the costs of supervising resident training at the nonhospital sites in order to count the residents for direct GME and IME purposes:

a) A physician receives a predetermined salary as compensation for working at a nonhospital site.
b) The compensation of a member of a group practice consists of a base salary, plus a percentage of revenues based on productivity (i.e., the number of patients he treats relative to other physicians in the practice), or seniority.
c) A physician that supervises residents is a member of a group practice. His compensation at the practice is based on the number of patients that he sees and for which he bills, plus additional compensation for other duties that he performs at the practice.
d) A physician is employed and paid by the State (or some other third party) to provide services in various state-owned nonhospital settings. The physician does not receive any predetermined compensation from the nonhospital settings themselves, and bills independently for the patients that she treats in these settings. At the request of Hospital A, the physician has agreed to teach several residents when she is working in some of these nonhospital settings. Hospital A would be required to pay the State (i.e., the employer of the physician) for the portion of the physician's salary attributable to GME activities at the applicable nonhospital sites. The written agreement(s) between the hospital and the State would list each clinic and would specify the amount of compensation attributable to each clinic (unless 42 CFR § 413.78(e) is applicable).

ATTACHMENT 2

1

Vinson & Elkins

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June 24, 1999

Ms. Rebecca Hirshorn
Health Care Financing Administration
7500 Security Blvd.
Mail Stop C4-07-07
Baltimore, Maryland 21244

Re: Calculation of FTE Count in Nonhospital Settings

Dear Ms. Hirshorn:

This letter is to confirm our conversation of last week regarding the calculation of the full-time equivalent ("FTE") resident count in nonhospital settings for determining direct ("GME") and indirect ("IME") graduate medical education payments. Specifically, 42 C.F.R. § 413.86(f)(4)(i) states that the time residents spend in nonhospital settings may be included in the FTE count and GME payment calculations if the residents spend their time in "patient care activities." The same requirement exists for IME payment calculations under 42 C.F.R. § 412.105(f)(1)(ii)(C). Based on our conversation, it is my understanding that the Health Care Financing Administration ("HCFA") interprets the phrase "patient care activities" broadly to encompass all patient care oriented activities that relate to the residency program, including, for example, resident participation in (1) the direct delivery of patient care, such as clinical rounds, discussions, and conferences, and (2) scholarly activities, such as educational seminars, classroom lectures, research conferences, patient care related research as part of the residency program, and presentations of papers and research results to fellow residents, medical students, and faculty. Accordingly, a hospital may include the entire time spent by residents in nonhospital settings in its FTE count and GME/IME payment calculations as long as the resident is involved in patient care oriented activities and other program requirements are met. If my understanding is incorrect, please notify me promptly at 713/758-3480.

Thank you for your assistance in this matter.

Very truly yours,

B. Scott McBride

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

SEP 24 1999

Mr. B. Scott McBride
Vinson & Elkins L.L.P.
2300 First City Tower
1001 Fannin Street
Houston, TX 77002-6760

Dear Mr. McBride:

This is in response to your letter regarding the calculation of full time equivalent (FTE) resident counts in nonhospital settings for determining direct (GME) and indirect (IME) graduate medical education payments. You specifically inquired about Health Care Financing Administration's (HCFA) interpretation of "patient care activities" in relation to the time residents spend in nonhospital sites.

HCFA interprets the phrase "patient care activities" broadly to include any patient care oriented activities that are part of the residency program. As you stated in your letter, this can include resident participation in "1) the direct delivery of patient care, such as clinical rounds, discussions, and conferences, and 2) scholarly activities, such as educational seminars, classroom lectures, research conferences, patient care related research as part of the residency program, and presentations of papers and research results to fellow residents, medical students, and faculty." Therefore, as long as the residents are primarily involved in patient care oriented activities and other program requirements are met, a hospital may include other educational activities as part of the entire time spent by residents in nonhospital settings and include this time in its FTE count and GME/IME payment calculations.

If you have further questions, please call Rebecca Hirshorn at 410-786-3411 or Michelle Lefkowitz at 410-786-5316 of my staff.

Sincerely,

Tzvi M. Hefter
Director
Division of Acute Care
Plan and Provider Purchasing Policy Group

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June 12, 2006

Mark B. McClelland, MD, PhD
Administrator
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7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1488-P Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClelland:

The American Nurses Association (ANA) appreciates the opportunity to submit comments on the proposed rule to make changes to Medicare's hospital inpatient prospective payment system for Federal fiscal year 2007. ANA, the only full-service professional organization representing the nation's registered nurses through its 54 constituent member nurses associations, advances the nursing profession by fostering high standards of nursing practice, promoting the rights of nurses in the workplace, projecting a positive and realistic view of nursing, and by advocating to Congress and regulatory agencies on health care issues affecting nurses and the public.

According to the 2004 National Sample Survey of Registered Nurses, 56.2 percent (1,360,965) of employed registered nurses work in hospitals. Some level of nursing care is an integral and necessary component of every patient's hospital stay. No other professional has direct bedside twenty-four hour accountability for care. Nursing care is one of the main reasons for admission to a hospital. Nursing accounts for nearly half of all the direct costs in hospitals. Yet the unique contributions of nursing care related to patient outcomes and the associated costs have gone largely unrecognized. At this time, as CMS solicits comments with recommendations to move to a true cost based system, ANA believes that nursing care should be a fundamental consideration of a revised payment system.

Section II: C. Proposals for Revisions to the DRG System Used Under the IPPS

When the diagnosis related group (DRG) payment system was first structured, it included nursing as a separate cost center for each facility, with modification of the DRG payment based on a formula derived in part from costs associated with nursing intensity at that facility. However, when the Medicare prospective payment system was implemented it did not include nursing intensity as a determining factor. Since the advent of the

prospective payment system, hospitals have experienced substantial increases of intensity of services and case-mix complexity and shorter lengths of stay. During this time, the Centers for Medicare and Medicaid Services (CMS) has missed opportunities to adjust hospital payments to incorporate nursing care as a separate cost entity within the inpatient prospective payment system. Now as CMS publishes a proposed rule that introduces a whole new calculation of weights and formulas to refine the system to include severity adjustment to the DRG system, ANA recognizes that a major overhaul of the hospital reimbursement system will take place and that this presents an opportunity to include nursing costs in the inpatient prospective payment system (IPPS).

The ANA urges CMS to seize this opportunity to make necessary corrections that will bring the DRG system into the 21st century model of care that recognizes that nursing care has an independent clinical and cost effective relationship to patient outcomes. The proposed move from a charge-based system of calculating the DRG weighting factors to one based on hospital specific costs opens the door to acknowledge the contribution of 1.4 million nurses working in U.S. hospitals. By explicitly including nursing intensity and nursing costs, hospital payments would more accurately match financing with actual patient care. Rolled into the flat room rate, the cost of nursing care becomes an aggregate expressed as average nursing hours per patient days. While other costs that fall under the room charge, such as housekeeping and overhead costs borne by the facility are more amenable to averaging, nursing care can vary dramatically among patients even on the same unit. Nursing care is a variable, rather than a fixed, cost function, for the facility's accounting purposes. It is illogical that nursing is reflected in the Medicare IPPS Case-mix weights only through flat room and board charges for any given DRG. The end result is that a significant amount of money is being misallocated across hospitals and types of hospitals for required nursing care. A national set on nursing intensity weights could correct this situation.

In particular, ANA strongly supports the arguments set out by John M. Welton, PhD, RN whose own comments in response to the current proposed rule offer recommendations to change the IPPS to better reflect the cost of care and to accommodate varying levels of severity of illness. His approach uses nursing care as the cost basis and nursing intensity as a measurement of both the severity of illness and the complexity of care. Specifically, ANA strongly recommends the following: the creation of a separate direct and indirect cost center at each provider hospital and inclusion of these data in the annual Medicare Cost Report: the collection and reporting of nursing intensity data: and the adjustment of the Medicare payment for severity of illness by modifying the proposed APR-DRG severity adjustment formula to incorporate nursing intensity and costs within each diagnosis and severity category.

The ANA recognizes that to successfully accomplish the above recommendations pilot testing and demonstration projects will be required. Fortunately work along these lines has already been initiated and could benefit from further development. In addition to the data and methodology in use at Medical University of South Carolina Medical Center as described by Dr.Welton in his comments, there is an alternative approach and potential model that has been developed and implemented in New York State.

The New York model was the first prospective payment system to include nursing explicitly in its payment formula. One of the key design features of the New York payment system is the explicit recognition of the relative nursing resource consumption levels among DRGs. The nursing intensity weights (NIWs), developed in collaboration between the New York State Department of Health and the New York State Nurses' Association, provide the means by which hospitals' routine nursing costs are allocated to patients and their corresponding DRGs. They are an integral component in determining the DRG service intensity weights used in calculating a hospital's reimbursement for Medicaid patients in New York State.

The NIWs were developed initially in 1984 by a special nursing panel convened by the New York State Nurses Association, and representatives of regions and types of hospitals in New York State. The basis of New York's DRG system is the same classification system established for purposes of reimbursement for hospital inpatient services for Medicare beneficiaries.

The NIWs developed by the original panel have been amended and reevaluated periodically to maintain consistency with changes in the DRG definitions. The most recent update was conducted in 2005 when the NWIs for all the existing DRGs and new DRGs were reviewed to reestablish proper relativity in a payment system which sets rates for billions of dollars in health care services and is also used by payers other than the State. Since this program has been successfully implemented in a large state for a number of years and there is data demonstrating its effectiveness, ANA recommends that the New York model be used as a prototype for a Medicare demonstration project and ANA stands ready to collaborate with CMS to work toward the development of national nursing intensity weights.

Section IV: M. Health Care Transparency Initiative

We appreciate and support the concepts expressed in the preamble to the rule related to the CMS Health Care Transparency Initiative. In the preamble, CMS announces that the Department of Health and Human Services intends to launch a major health care information transparency initiative in 2006 building on existing programs to make quality and price information available to the health care consumer. It describes various options such as publishing lists of hospital charges for different regions of the country, or publishing various rates that Medicare reimburses a particular hospital for selected DRGs or requiring hospitals to post their prices and/or discount policies. In that section CMS stresses the importance of transparency of medical billing in order to help consumers understand the cost of the services they receive; it argues that "part of the reason health care costs are rising so quickly is that most consumers –the patients- are frequently unaware of the actual cost of their care." The proposed rule, however, fails to identify and include the cost of nursing care as part of the information shared with the patient which is antithetical to the entire premise of transparency underlying all of these Administration initiatives. If CMS chooses not to modify the IPPS to include nursing as a separate cost

center, ANA believes that a full explanation is required as to how that decision can be aligned with the Administration's other initiatives regarding honest pricing and cost information for health care consumers.

Section IV: J. Hospital Emergency Services Under EMTALA

The ANA agrees with the conclusion of the EMTALA TAG and CMS that the requirement for certification of "false labor" by a physician is overly prescriptive, and that properly qualified health care practitioners other than physicians should be permitted to conduct this screening examination. However, the proposed language of §489.24(b) ignores the distinctions made elsewhere in the statute and regulations between physicians and health care practitioners, medical services and health care services. By the use of the word "medical," the proposed language could be used in an exclusionary manner clearly not intended.

Thus, we propose a refinement in the wording to more accurately reflect the intention of both the TAG and CMS, as set out in the Preamble:

§489.24(b) "... A woman experiencing contractions is in true labor *unless a physician, certified nurse-midwife, or other qualified health care professional (as determined by the hospital in its bylaws or rules and regulations) acting within his or her scope of practice as defined by State law, certifies that*, after a reasonable time of observation, the woman is in false labor."

Conclusion

Thank you for this opportunity to present our views. We would be happy to work with CMS on any of the issues discussed above or other topics that involve nurses or nursing care. If you have questions concerning these comments, please feel free to call me or Sheila Abood, PhD, RN Associate Director Government Affairs who can be reached at 301-628-5093.

Sincerely,

Rose Gonzalez, MPS, RN
Director, Government Affairs

178

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N•A•C•H••••••••••••••••••••••••••••••••••••••

June 12, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Hospital IPPS Rule
Hospital-within-a-Hospital Provisions

Dear Secretary Leavitt:

These comments are being submitted by the National Association of Children's Hospitals ("N.A.C.H."). N.A.C.H. represents more than 130 children's hospitals across the country, including independent children's acute care and specialty hospitals as well as children's hospitals within larger hospitals and health systems. The N.A.C.H. membership includes most of the 82 children's hospitals that are exempt from Medicare's acute care inpatient hospital prospective payment system ("IPPS"), as identified by the Centers for Medicare and Medicaid Services (CMS). Medicare IPPS-exempt children's hospitals include both free-standing children's hospitals and children's hospitals-within-hospitals.

Please note that the N.A.C.H. comments are independent of those submitted by our sister organization, the National Association of Children's Hospitals and Related Institutions (NACHRI). N.A.C.H. and NACHRI are each submitting comments on different policy issues raised in CMS's proposed rule changes on the Medicare IPPS.

N.A.C.H.'s comments address the CMS proposal to modify the grandfathering provisions of the "hospital-within-a-hospital" rule appearing at 42 C.F.R. § 412.22(f). As CMS states in the preamble, it "has been urged to modify [its] policies to allow these grandfathered entities to increase in square footage and number of beds without requiring compliance with the 'separateness and control policies.'"

There are three children's hospitals-within-hospitals that will be adversely affected by the rule barring grandfathered hospitals-within-hospitals from increasing in square footage or bed size: CHRISTUS Santa Rosa Children's Hospital in San Antonio; TX, Rainbow Babies and Children's Hospital in Cleveland, OH; and Tod Children's

Hospital in Youngstown, OH. These three children's hospitals are grandfathered under CMS' hospital-within-a-hospital rule and are excluded from the IPPS.

Under the amendment to the hospital-within-a-hospital rule promulgated by CMS in 2003, however, these hospitals will lose their grandfathered status and their IPPS-exclusion if they change their bed count or square footage. *See* 68 Fed. Reg. 45346, 45463 (Aug. 1, 2003). If these hospitals do not meet the requirements for exclusion under the hospital-within-a-hospital rule, the loss of their grandfathered status would mean that these children's hospitals would be treated as hospitals subject to IPPS.

While these hospitals' status has only a very limited effect on payments by Medicare, as explained below, the hospitals are at risk of being adversely affected under both state Medicaid programs and the Health Resources and Services Administration's ("HRSA") Children's Hospitals Graduate Medical Education ("CHGME") program. Qualifying as a children's hospital under the Medicare regulations for hospitals excluded from IPPS is a prerequisite for receiving specific payment adjustments under their state Medicaid programs, and it is also a requirement for receiving federal CHGME payments.

These three hospitals need to expand the services that they provide in order to continue to provide quality care to children from their regions and to meet growing demand for their services. In order to do so, the hospitals must either (a) give up their grandfathered status and be paid under IPPS or (b) meet the requirements of the hospital-within-a-hospital rule for exclusion from IPPS. Neither alternative is feasible and we believe that the proposed rule should be amended to create an exception for children's hospitals to the restrictions applicable to grandfathered hospitals-within-hospitals.

CMS has articulated three reasons for the restrictions it has placed on grandfathered hospitals-within-a-hospital: 1) to prevent the proliferation of long term care hospitals-within-hospitals that function as hospital units, 2) to prevent the avoidance of TEFRA target rates and 3) to avoid two payments by Medicare for one episode of care.

There is no proliferation of children's hospitals-within-hospitals; to the best of our knowledge, there are only three such grandfathered facilities in the country. Each of the three was organized as a hospital-within-a-hospital at least 30 years ago, long before this structure had any relevance for payment purposes. None of the three grandfathered children's hospitals-within-hospitals has reorganized since 1982 and thus, none has manipulated or changed its TEFRA target rate by operating as a hospital-within-a-hospital. Since children are almost always admitted directly to children's hospitals, there should be no concern about two hospital payments for a single spell of illness.

None of the reasons that CMS has advanced in support of restricting hospitals-within-hospitals applies to grandfathered children's hospitals. Moreover, Medicare utilization

of children's hospitals is negligible. No legitimate public policy purpose is advanced by preventing grandfathered children's hospitals from making needed changes to their physical plants.

CMS applies the same restrictions to satellite facilities as it does to hospitals-within-hospitals. Yet, children's hospitals are expressly excepted from the restrictions on grandfathered status under the satellite facilities regulation. In the preamble to the 2006 proposed rule, CMS logically notes that it should make consistent the grandfathering provisions of the hospital-within-a-hospital rule with the grandfathering provisions of the satellite hospital rule. If CMS follows its own suggestion, it will except children's hospitals from the restrictions on grandfathered hospitals in the hospital-within-a-hospital rule.

In prior discussions on this issue, CMS staff has questioned the effect of restrictions on the grandfathered status on these three hospitals and has suggested that the restrictions could be avoided. The three children's hospitals have examined that issue closely and do not believe that the restrictions on grandfathered facilities can be avoided easily, and that doing so would increase costs by millions of dollars in connection with the refinancing of debt, without taking into consideration the loss of other efficiencies.

Accordingly, N.A.C.H. requests that CMS create an exception to the hospital-within-a-hospital grandfathering provision for children's hospitals, which will allow them to both increase their bed size and square footage and retain their IPPS exclusion.

I. BACKGROUND OF THE HOSPITAL-WITHIN-A-HOSPITAL RULE AND GRANDFATHERING PROVISION

From the beginning of the acute care IPPS in the 1980s, CMS has excluded children's hospitals. 49 Fed. Reg. 234, 235-36 (Jan. 3, 1984); *see also* Social Security Act § 1886(d)(1)(B).

In the 1990s, there was a proliferation of long term acute care hospitals (LTCH) within hospitals. At the time, the Health Care Financing Administration (HCFA) characterized these LTCHs-within-hospitals as operating as excluded units of acute care hospitals, even though the only excluded units provided for by law were those furnishing psychiatric or rehabilitation services.

In 1994, HCFA enacted a rule that established a set of requirements that long term acute care hospitals-within-hospitals must meet in order to be excluded from IPPS. HCFA's stated purpose in promulgating the 1994 amendment was to prevent what is functionally a "unit" of a hospital from being excluded from IPPS through certification as a separate hospital (i.e., a hospital-within-a-hospital). The preamble to the rule stated:

> [E]xclusion of long-term care "units" is inconsistent with the statutory scheme....[T]he statute does not provide for exclusion of long-term care units. Because we believe such exclusions are contrary to the purpose and scheme of section 1886(d)(1)(B) of the Act, we proposed to revise the regulations to prevent inappropriate exclusions.
>
> To avoid recognizing nominal hospitals, while allowing adequate flexibility for legitimate networking and sharing of services, we proposed [the regulation that set forth certain standards that an LTCH had to meet to be excluded from IPPS when it was a "hospital within a hospital."]

59 Fed. Reg. 45330, 45389 (Sept. 1, 1994).

In 1997, HCFA extended the hospital-within-a-hospital regulation to apply to all categories of IPPS-excluded hospitals, including children's hospitals. In the proposed rule, HCFA explained that it was concerned that rehabilitation and psychiatric excluded units were being closed and then re-established as rehabilitation and psychiatric hospitals-within-hospitals in order to take advantage of new, more favorable TEFRA target rates:

> It has become apparent that, while rehabilitation and psychiatric facilities may be granted exemptions from the PPS as units of larger hospitals, there may be cases where such facilities may rather seek exclusion as hospitals-within-hospitals in order to take advantage of certain payment rules that favor hospitals. [For example, new hospitals-within-hospitals qualify for the new hospital exemption from the rate of increase ceiling, which is not available to new units....

62 Fed. Reg. 29902, 29929 (June 2, 1997); *see also* 62 Fed. Reg. 45966, 46014 (Aug. 29, 1997).

Subsequent to the regulatory amendments in the 1990s, CMS has also explained that one purpose of the rule is to prevent having "two Medicare payments for what was essentially one episode of patient care." 71 Fed. Reg. 23995, 24124 (Apr. 25, 2006), quoting 69 Fed. Reg. 48916, 49191 (Aug. 11, 2004).

In summation, CMS has articulated three problems that the hospital-within-a-hospital rule addresses:

1. the proliferation of LTCHs within hospitals even though such LTCHs were actually operating as "units,"

2. evasion of TEFRA target rate ceilings applicable to excluded hospital units by opening excluded psychiatric and rehabilitation hospitals-within-hospitals, and

3. the making of two payments by Medicare for what is essentially one episode of care.

CMS has not articulated any other purpose for its limitations on excluded hospitals-within-hospitals.

II. INAPPLICABILITY TO CHILDREN'S HOSPITALS OF CMS' RATIONALE FOR LIMITING EXCLUDED HOSPITALS-WITHIN-HOSPITALS

None of the rationales supporting the hospital-within-a hospital rule applies to children's hospitals. There has been no proliferation of children's hospitals-within-hospitals; the grandfathered children's hospitals-within-hospitals are not evading TEFRA target rate limitations; and neither Medicare nor any other payer is making two payments for what is essentially one episode of care.

A. No Proliferation of Children's Hospitals-Within-Hospitals

After inquiry and to the best of N.A.C.H.'s knowledge, there are only three grandfathered children's hospitals-within-hospitals in the country. Each of the three hospitals is substantial: CHRISTUS Santa Rosa Children's – 276 beds, Rainbow Babies and Children's Hospital – 226 beds, and Tod Children's Hospital – 91 beds. Each of the three institutions has substantial name recognition within its region and a separate identity that that makes clear it is a children's hospital, not simply a pediatric department of the hospital with which it shares a campus. The three children's hospitals stand in marked contrast to the LTCHs that were proliferating in the early 1990s, which were often a couple of dozen beds or fewer located in the wing of the principal hospital building. As CMS' own data for 2003 shows, "long stay" hospitals (excluding psychiatric hospitals) have, on average, fewer than 50 beds.[1]

B. Grandfathered Children's Hospitals Are Not Evading Medicare TEFRA Target Rate Limitations

The three grandfathered children's hospitals-within-hospitals do not have incentives to avoid TEFRA rate limitations for the obvious reason that Medicare reimbursement is immaterial for these hospitals. None of these hospitals has a Medicare utilization rate greater than one percent. In any event, each of these hospitals was created prior to the inception of the TEFRA target rate methodology for payment, and none of the three has changed the manner in which it has been organized since the inception of the TEFRA rate methodology. Accordingly, these children's hospitals-within-hospitals

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[1] According to CMS' data, in 2003 there were 1306 "long stay" hospitals with a total of 62,000 beds, i.e., fewer than 50 beds per hospital. http://www.cms.hhs.gov/DataCompendium/02_2003_Data_Compendium.asp#TopOfPage.

have the same TEFRA base period and rate that they have always had ; they have not in any way evaded or manipulated the TEFRA target rate limitations.

Indeed, since these hospitals are excluded from IPPS, Medicare is paying *less* than if these hospitals were not excluded from IPPS. Each of these three hospitals participates in graduate medical education programs. If the residents at these three children's hospitals could be counted by the acute care hospital on the same campus, Medicare would make substantial additional payments for the direct and indirect costs of graduate medical education.

In short, expansion of any grandfathered children's hospital will not "increase their Medicare payments," which is the stated reason for limiting the addition of beds or square footage for grandfathered hospitals. 71 Fed. Reg. at 24125.

C. Medicare Will Not Pay Twice for a Single Episode of Care

Finally, with respect to these three grandfathered children's hospitals, there is no concern that Medicare (or anyone else) will pay twice for the same care. Children are admitted directly to these hospitals; it is rare that a child is admitted at the co-located hospital and then transferred to the children's hospital. The only exception is for neonates who are transferred.[2] The appropriateness of those babies being treated in a neonatal intensive care unit is clear.

III. ADVERSE IMPACT OF MEDICARE RULE ON CHILDREN'S HOSPITALS

A. Relevance of Medicare "Excluded" Status to Children's Hospitals

In 2003, CMS limited grandfathered status to hospitals that made no changes in bed size or square footage. CMS explained the rationale in the preamble to the rule:

> The intent of the grandfathering provision was to ensure that hospitals that had been in existence prior to the effective date of our hospital-within-a-hospital requirements should not be adversely affected by those requirements. To the extent hospitals were already operating as hospitals-within-hospitals without meeting those requirements, we believe it is appropriate to limit the grandfathering provision to those hospitals that continue to operate in the same manner as they had operated prior to the effective date of the those rules. However, if a hospital changes the way it operates (for example, adds more beds) subsequent to the effective date of the new rules, it should no longer receive the benefit of the grandfathering provision.

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[2] Under EMTALA, these hospitals have an affirmative obligation to accept such transfers.

68 Fed. Reg. 45346, 45463 (Aug. 1, 2003). In the final IPPS rulemaking for fiscal year 2003, CMS stated that it planned to review whether further revisions to the provision should be made to allow more changes in operation by grandfathered hospitals-within-hospitals and that the agency would "welcome specific suggestions on this issue." *Id.* Notwithstanding CMS' statement that its intent was "to ensure" that grandfathered hospitals "not be adversely affected," the limitation on grandfathered status does adversely affect the three children's hospitals and their communities because they cannot meet the increased demand for their services and accommodate new technologies without increasing bed size and square footage.

As discussed above, children's hospitals receive virtually no Medicare payment because they rarely treat patients eligible for payment under Title XVIII. On average, independent acute care children's teaching hospitals operating with their own Medicare provider number devote less than one percent of their patient care to patients eligible for Medicare—i.e., primarily children with end stage renal disease.

Although there is virtually no Medicare utilization at children's hospitals, children's hospitals can be adversely affected by the Medicare rules because Medicare affects payment to children's hospitals through the federal CHGME program. In order to receive CHGME payments, a hospital must be excluded from the Medicare IPPS. 66 Fed. Reg. 12940, 12941 (Mar. 1, 2001). In fiscal year 2005, CHRISTUS Santa Rosa Children's Hospital received $1,037,444; Rainbow Babies and Children's Hospital received $4,846,380; and Tod Children's Hospital received $1,323,405 from the CHGME Program. *See* "HHS Provides $288.4 Million to Children's Hospitals to Support Graduate Medical Education Programs," *available at* http://bhpr.hrsa.gov/childrenshospitalgme/2005payments.htm. (Since Congress did not authorize CHGME payments until 2000, these hospitals whose organizational structures date back at least 30 years did not become hospitals-within-hospitals in order to qualify for CHGME payments.)

In addition, both Ohio and Texas Medicaid programs reimburse children's hospitals excluded from Medicare hospital IPPS at more appropriate rates, relative to costs, than they otherwise would receive. Texas Medicaid reimburses inpatient care using a DRG-based prospective payment system but employs an alternative payment system for Medicare IPPS excluded children's hospitals. Ohio Medicaid has modified its DRG-based IPPS reimbursement system so that each Medicare IPPS excluded children's hospital is its own peer group for purposes of calculating its Medicaid reimbursement rates. At the time that the last of these three hospitals was organized as what is now called a "hospital within a hospital," federal law required state Medicaid programs to pay all acute care hospitals on a reasonable cost basis.[3]

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3 Congress did not amend Title XIX until 1981 to permit other than reasonable cost payments to hospitals. Pub. L. 97-35 § 2173(a)(1)(B).

In prior communications, CMS staff has advised the three hospitals that it was appropriate for CMS to consider the effect of its Medicare policies on Medicaid payment. We note that each of these hospitals was organized as a children's hospital-within-a-hospital prior many years ago, long before the hospital-within-hospital rules were proposed. In addition, Medicaid policy makers in Texas and Ohio have designed provisions for children's hospitals including these hospitals knowing how they are organized and operated on the same campus as another hospital. Those state plan provisions have been approved by CMS. Just like other provisions of state Medicaid plans, CMS may trust to the states the particulars of how the states choose to pay for services furnished by these hospitals.

Thus, if these three hospitals lose their grandfathered status under the hospital-within-a-hospital rule, the effect would be severe and would likely impact these hospitals' ability to serve the needs of sick children in their communities. All are major safety net providers to children of low-income families.

B. Maintaining Excluded Status under the Current Regulation Presents the Choice between Two Unacceptable Alternatives—Either Not Changing Bed Size/ Square Footage or Changing Legal Structure and Control

For each of the three hospitals to maintain its current status as a hospital excluded from IPPS under the current hospital-with-a-hospital rule, these hospitals must either freeze their current bed count and square footage indefinitely or change their governance structure so that neither the co-located hospital nor any organization related to the co-located hospital controls the children's hospital. Neither of those alternatives under the current rule is acceptable.

1. The Premise of the Rule is Flawed

The premise of the rule – that a change in square footage or bed size means that a children's hospital would not be "operat[ing] in the same manner" – is flawed. Many hospitals routinely change bed size and square footage to accommodate changes in demand as well as continuous changes in how health care is delivered.[4] There is no reason to suggest that an increase in the number of beds or an increase in the square footage of a children's hospital in some way equates to a "change in the way it operates," as suggested in the 2003 preamble. There is no inherent reason why updating a facility to accommodate increased demand or changes in the manner in which services are delivered would prevent any of the three hospitals-within-hospitals from being able to "operate in the same manner" as it had operated prior to the project, affecting its facility or the effective date of grandfathered status in 1997.

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4 As just a single example, there continues to be a migration of services from the inpatient setting to the outpatient setting that is reflected in hospitals all over the country increasing the space available for outpatient services.

In the recently published IPPS proposed rule for fiscal year 2007, CMS proposed very slight relaxation of the restrictions applying to "grandfathered hospitals." 71 Fed. Reg. 23996, 24124 (Apr. 25, 2006). These proposed revisions will not permit the majority of changes that these three hospitals need to make to meet the needs of their communities. CMS has not explained in the preamble why some changes to bed size or square footage apparently do not prevent a "grandfathered hospital" from operating "in the same manner" as it had previously, the standard that CMS articulated in 2003, while other changes prevent that. Thus, without rational explanation under CMS' proposal, the grandfathering provision would adversely affect and target children's hospitals-within-hospitals that increase their bed count or square footage.

2. These Three Hospitals Cannot Serve Their Communities Without Updating Their Physical Plants

Requiring the children's hospitals to freeze their current bed count and square footage will interfere with the hospitals' ability to effectively treat the children in their communities. Each of the three hospitals is facing growing pressure to expand its bed count and increase the level of services that it provides to children throughout its community. In separate comment letters, the hospitals will explain the growth in demand in its service area and why changing bed size and square footage is necessary. But CMS has sufficient familiarity with hospital services to know that a hospital cannot continue to operate efficiently and effectively if its physical plant is locked into the configuration from 1997; indeed at least one of these hospitals is operating in a plant that dates back many decades.

3. Changing Governance and Legal Structure Is Impractical and Costly, and Doing So Would Serve No Legitimate Interest of the Medicare Program

In the preamble to the proposed rule, CMS has stated that if a grandfathered hospital-within-a-hospital "chooses not to operate under the same terms and conditions in effect as of its grandfathering, it could still be paid under the applicable excluded hospital payment system if it changed its relationship with its host to the extent that it has come into compliance with the separateness and control requirements." 71 Fed. Reg. 23996, 24125 (Apr. 25, 2006). CMS personnel have made the same suggestion in a prior meeting with representatives of the three adversely affected children's hospitals. These three hospitals have evaluated the feasibility of changing their legal structure so as to meet the separate governance requirement in the hospital-within-a-hospital regulation and have concluded that it is not practical to meet this standard.

According to Medicare rules, in order for a hospital-within-a-hospital to qualify for exclusion from IPPS, the hospital must have a separate governing body that "is not under the control of the hospital occupying space in the same building or on the same campus, or of any third entity that controls both hospitals." 42 C.F.R. §

412.22(e)(1)(i). "Control" is defined as existing "if an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution." 42 C.F.R. § 412.22(g). This is the same definition of control that is in Medicare's "related organization principle," now codified at 42 C.F.R. § 413.17.

"Control" is generally found to exist where there is 20 percent or more voting power, but it also has been found to exist when there is less than 20 percent voting power based on specific facts and circumstances. There is no safe harbor threshold under which one can be absolutely sure that control will not be found to exist when there is any interlocking of officers or directors.

It is not feasible for these children's hospitals to satisfy the very strict Medicare definition of control, because each reports to the governing boards of larger systems that include both the children's hospital and the co-located hospital. The common control that presently exists between these children's hospitals and their co-located hospitals is desired. These relationships go back many decades, where there has been a symbiotic relationship between the children's hospitals and their co-located hospitals. A required arbitrary change to their organizational structure would be inappropriately disruptive to the hospitals and their communities. This is not just a matter of history; it is also a matter of operating efficiency. There is no point in severing these longstanding ties since the Medicare program is not adversely affected if these hospitals are under the common control with the co-located hospitals.

Presently, all three hospitals have outstanding bond debt and all three contemplate additional borrowing for needed capital projects. A legal reorganization changing the control of the hospitals so that they meet the separateness standard in the regulation would violate covenants in existing debt. The cost of refinancing alone would run into millions of dollars. In addition, it is likely that the applicable interest rate would be higher as well, which would increase costs by additional millions of dollars.

If these hospitals were allowed to increase their bed count and square footage, there would be virtually no additional costs to the Medicare program. In the April 2006 proposed rulemaking, CMS recognized that under certain circumstances, a change in a hospital's bed count or square footage will result in no additional costs to the Medicare program, and CMS has proposed an exception to the "no change" policy of the grandfathering provision to allow for such changes. A similar situation exists for children's hospitals seeking to increase their bed counts and square footage. Because these hospitals treat a miniscule number of Medicare patients, an increase in their bed count or square footage would have de minimis effect on the Medicare program.

4. Obtaining Services from the Co-Located Hospital Is Also Not a Feasible Option

In a prior meeting with CMS staff, the three hospitals were advised that grandfathered children's hospitals could avoid the adverse effects of the limitations on grandfathered status through purchasing services "under arrangements" from the co-located hospital.

The concept of furnishing services "under arrangements" is not infinitely elastic. CMS' own regulations limit coverage for "under arrangement" services furnished to outpatients if the services are not furnished in the hospital's own certified space. 42 C.F.R. § 410.27(f). In addition, it is not clear that the patient is properly billed as a children's hospital patient at all if the patient is not physically housed in that hospital.[5] In addition, Medicare's survey and certification rules as well as state licensure rules require separateness between separate hospitals. Thus, there will be walls, doors and separate entrances for separate hospitals. These physical barriers will interfere with furnishing care.

All of the personnel at a children's hospital are trained and experienced in dealing with children; personnel at a co-located hospital do not necessarily have that training and experience. When patients are concurrently receiving services from two institutions, there is inefficiency because there will be two medical records, and a much greater need for coordination and communication than if the patient is within one hospital with one computer system and system of records. These are not just efficiency issues but could also pose greater risk for errors to be made in furnishing care, to the detriment of patient safety. In short, there are substantial legal and practical obstacles to avoiding needed changes in physical plant by obtaining services from a co-located hospital.

IV. CMS SHOULD BE CONSISTENT AND EXTEND THE EXCEPTION FOR CHILDREN'S HOSPITALS IN THE SATELLITE HOSPITAL RULE TO THE HOSPITAL-WITHIN-A HOSPITAL RULE

In the proposed rule, CMS stated that there should be consistency between the rules governing satellite facilities and hospitals-within-hospitals:

> Because the underlying rationale for the grandfathering policies for both hospitals- within-hospitals and satellite facilities of hospitals-within-hospitals is the same, upon review of these various provisions, we believe that, where appropriate, *the grandfathering provisions should be consistent*.

5 It is conceivable that CMS could characterize some arrangements to house patients in a co-located hospital as a satellite hospital arrangement that does not comport with the satellite hospital rules at 42 C.F.R. § 412.22(h).

71 Fed. Reg. at 24125 (emphasis added). We agree with CMS that there should be consistency between the grandfathering provisions of the hospital-within-a hospital rule and the satellite hospital rule.

Children's hospitals are excepted from the restrictions on grandfathering facilities in the satellite hospital rule, 42 C.F.R. § 412.22(h)(1)(i). To bring about the consistency that CMS, itself, says is logical, children's hospitals should also be excepted from the limitations on grandfathered facilities under the hospital-within-a-hospital rule. When CMS created an exception to the restrictions on grandfathered satellite facilities of children's hospitals, CMS explained its rationale:

> We are not applying this requirement [the bar on increasing bed size above the number of beds certified prior to October 1, 1997 in a hospital that operates a satellite facility] to children's hospitals since those hospitals are not subject to caps established by the BBA [i.e., the 1997 Balanced Budget Act].

64 Fed. Reg. 41490, 41534 (July 30, 1999).

CMS' logic for exempting children's hospitals from the bar on changing their size under the satellite hospital rule should also be applied to the bar on changing size in the hospital-within-a-hospital provision of the same regulation. There is no rational basis for having the exception for children's hospitals in the satellite hospital definition and the lack of such an exception in the hospital-within-a-hospital provision. Satellite facilities are, in essence, a subset of hospitals-within-hospitals.[6] As reflected in the quotation above from the 1999 preamble, CMS' reason for creating standards for satellite facilities was the same as for hospitals-within-hospitals; satellite facilities were being created to evade TEFRA target rate limitations.

CMS has cited the same reason for restricting when a satellite facility may be excluded from the prospective payments system as it has for when a hospital-within-a-hospital may be excluded form the prospective payment system. CMS also has noted that it is appropriate to have consistency in the treatment of hospitals-within-hospitals. Therefore, the compelling reasons for an exception for the three grandfathered children's hospitals-within-a-hospital should be recognized in the final rule.

The satellite hospital exception for children's hospitals is entirely consistent with recognition elsewhere in the statutes and regulations of the uniqueness of children's hospitals. Congress recognized that children's hospitals are different in the 1983 amendments to the law that created IPPS. Congress enacted the CHGME program for children's hospitals because children's hospitals differ from all other types of hospitals in that they treat a very limited number of Medicare patients. As a result, they do not

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6 What distinguishes a satellite facility from a hospital-within-a-hospital is that a satellite facility, while co-located with one hospital, is controlled and operated as part of another hospital located elsewhere.

benefit from the significant Medicare payments for the types of graduate medical education that other IPPS hospitals receive.

CMS should continue to grandfather these facilities and create an exception for children's hospitals to the "no change" policy because: (1) the Medicare payments to these hospitals are immeasurably small in the context of Medicare payments to other types of hospitals; (2) these hospitals have not attempted to abuse their PPS-excluded status; (3) there is no prospective opportunity to manipulate the TEFRA target rate of increased ceiling through continued operation of these grandfathered facilities even if there is a change in bed size or square footage; and (4) the three children's hospitals' existence long precedes IPPS rules – their creation was based on the needs of the children of their communities, not gaming Medicare IPPS payment rules. In addition, creating the requested exception would bring consistency between the satellite facility and hospital-within-a-hospital rule in accordance with CMS' expressly stated intent.

V. RECOMMENDATION FOR REGUATORY AMENDMENT

On behalf of the three affected children's hospitals, we recommend the following regulatory language to address their situation.

> (f) *Application for certain hospitals.* Except as provided in paragraph (f)(3) of this section, if a hospital was excluded from the prospective payment systems under the provisions of this section on or before September 30, 1995, and at that time occupied space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital, the criteria in paragraph (e) of this section do not apply to the hospital as long as the hospital --
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> * * * * *
>
> (3) **Is a children's hospital; or**
>
> (4) For cost reporting periods beginning on or after October 1, 2006, in applying the provisions of paragraph (f)(1) or (f)(2) of this section, any hospital that was excluded from the prospective payment systems under the provisions of this section on or before September 30, 1995, and at that time occupied space in a building also used by another hospital, or in one or more buildings located on the same campus as buildings used by another hospital --

This proposal would be consistent with the simple exception for children's hospitals that presently appears in the satellite hospital regulation. However, to the extent that CMS has any concerns about the scope of this proposal, it could limit further the exception to children's hospitals-within-hospitals that were in existence prior to the

inception of IPPS.

VI. CONCLUSION

In conclusion, there are five reasons CMS should extend its proposed amendments to the hospital-within-a-hospital grandfathering provision to allow grandfathered children's hospitals either to *increase or decrease* their bed counts and/or square footage:

- Children's hospitals do not contribute to any of the problems that the rule against change in grandfathered hospitals-within-hospitals is designed to address. They do not contribute to the proliferation of long term care hospitals-within-hospitals. They do not contribute to evasion of TEFRA payment limits. And they do not contribute to hospitals billing twice for what is essentially one episode of care, because patients seldom move betw3een the children's hospital and the co-located acute care hospital. Indeed, all three children's hospital existed prior to the establishment of the Medicare IPPS.

- There is no material benefit to Medicare from applying the prohibition against growth or change in bed size and square footage to the children's hospitals. There are only three affected hospitals and each devotes less than one percent of its patient care to children covered by Medicare. Similarly, there is no material benefit to Medicaid. While each of the hospitals is a major Medicaid provider, its size does not determine whether a pediatric patients I Medicaid eligible or not. And since federal funding for state Medicaid disproportionate share hospital payments is capped, the growth in these hospitals' Medicaid service could not cause the states to exceed their caps.

- There is substantial material harm to each of these hospitals and the children of their communities if the prohibition on growth or change were to continue to be applied to them. The children's hospitals' loss of Medicare IPPS-exempt children's hospital status would trigger their loss of millions of dollars of federal and state payment adjustments. As major safety net providers to children of low-income families, the loss of such funding would seriously affect their ability to continue to serve all children.

- The alternatives that hospitals might pursue to retain their Medicare IPPS-exempt status, such as change in governance or execution of expansion under the Medicare provider number of the co-located hospital pose serious legal, operational, and financial barriers, which the hospitals have found, after careful review, to be insurmountable.

- There are ample precedents in federal law and policy for exempting or treating children's hospitals differently when it comes to the application of Medicare payment policy to them. Most relevant is the fact that Medicare policy already exempts children's hospitals from the application of the 1999 growth limits on hospital satellite facilities. Because one of its stated goals is to bring the growth limits on satellite facilities and the growth limits on grandfathered hospitals-within-hospitals into greater conformity, CMS should exclude children's hospitals from the limits on grandfathered hospitals.

Thank you again for considering our comments. For further information, please contact me at 703/797-6006 or pwillson@nachri.org.

Sincerely,

Peters D. Willson

Peters D. Willson
Vice President for Public Policy

cc: Leslie Norwalk, Herb Kuhn, Tzvi Hefter, and Liz Richter, CMS
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June 9, 2006

VIA HAND DELIVERY
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Washington, DC 20201

Attention: File Code: CMS-1488-P

Re: Geographic Reclassifications; Comments to the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

File Code: CMS-1488-P

Ladies and Gentlemen:

We appreciate the opportunity to provide comments on behalf of Evanston Northwestern Healthcare Corporation ("ENH"), a multicampus hospital with a single provider number, and Highland Park Hospital, its campus in Lake County, Illinois, to the recently published Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year ("FY") 2007 Rates (the "Proposed 2007 Rule").[1] ENH believes it is important to make permanent a special rule for submission of wage data by a campus of a multicampus hospital for geographic reclassification. Otherwise, Highland Park Hospital will be directly and adversely affected by the CMS Proposed 2007 Rule regarding multicampus hospitals.

In the Proposed 2007 Rule, CMS proposes not to extend beyond FY 2008 the regulation at 42 C.F.R. § 412.230(d)(2)(iii), which provides a mechanism for a campus of a multicampus hospital to apply for reclassification to the metropolitan division where the other campuses are located. That section permits a campus of a multicampus hospital to submit composite wage data for the entire multicampus hospital in its application for reclassification.

[1]Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule, 71 FED. REG. 24095 (April 25, 2006) [hereinafter, the "Proposed 2007 Rule"].

Without § 412.230(d)(2)(iii), a campus of a multicampus hospital that is located in a metropolitan division different from its other campuses loses the right to seek reclassification because it does not have campus-specific wage data. Beginning with reclassification requests for FY 2009, a campus of a multicampus hospital would have to obtain a separate provider number, file a separate cost report, and accumulate five years of wage data in order to apply to the Medicare Geographic Classification Review Board ("MGCRB") for reclassification.[2] The Preamble to the Proposed 2007 Rule implies that without the special rule a campus of a multicampus hospital may still apply for reclassification in a county group application without applying for a separate provider number but the regulations themselves do not appear to support that position.

Two reasons are given for not continuing the rule. The first is that CMS believes that a campus should be required to use campus-specific data. It is our understanding that this is a perceived fairness issue. The second is that only one hospital, Highland Park Hospital, made use of the rule, and this hospital has since successfully applied for reclassification with other hospitals in the county in which it is located, with the implication that the regulation is not needed for a group application. Based on these reasons, CMS concludes that the special rule is no longer needed. Respectfully, we disagree.

Not extending the special rule may cause significant problems for Highland Park Hospital and ENH as well as other Lake County hospitals and, in the future, may cause significant problems for other multicampus hospitals. Highland Park Hospital and similarly situated hospitals would not be able to apply for reclassification to the wage index area where their other campuses are located either individually or in a group application. ENH urges CMS to reconsider its proposal and make § 412.230(d)(2)(iii) permanent. In the alternative, ENH urges CMS to promulgate a new rule that will allow a campus of a multicampus hospital to submit hospital-specific wage data on a supplemental form without filing a separate cost report or obtaining a new provider number (with an extension of § 412.230(d)(2)(iii) until the supplemental form data becomes official).

Background

Highland Park Hospital, located in Lake County, Illinois, is one of three hospital campuses operated by ENH, a not-for-profit health system. The three campuses are Highland Park Hospital, located in Lake County, Illinois, and Evanston and Glenbrook Hospitals, both located in Cook County, Illinois. Highland Park Hospital merged into ENH effective January 1, 2000, at a time when all three campuses were located in the same wage index area. At the time of the merger, CMS terminated Highland Park Hospital's former provider number and authorized Highland Park Hospital to use the ENH provider number as of the merger date. Highland Park Hospital became a campus of the multicampus ENH system, operating as a fully

[2] *Id.*

integrated component of the ENH system. All Highland Park Hospital wage data is reported on the single ENH cost report.

As a result of changes made by the Office of Management and Budget ("OMB") after the 2000 census and adopted by CMS, effective October 1, 2004, for Medicare payment systems, Lake County, Illinois, where Highland Park Hospital is located, was lopped off and paired with more rural Kenosha County, Wisconsin to form the Lake County, Illinois-Kenosha County, Wisconsin Metropolitan Division. All of the other constituent counties that formed the former Chicago statistical area are now in the Chicago Metropolitan Division.

After discussions and comments submitted to CMS on behalf of Highland Park Hospital, CMS recognized that the criteria for reclassification of hospitals to another wage area at the time of the adoption of the OMB changes did not address the situation of a single campus of a multicampus hospital seeking reclassification.[3] CMS requires a multicampus hospital to report data for the entire hospital on a single cost report. As a result, there was no wage survey data for the individual campus as was required by § 412.230 of the reclassification regulations. Without hospital specific data, MGCRB would not reclassify Highland Park Hospital. Recognizing this, CMS promulgated a regulation permitting a campus of a multicampus hospital to use the average hourly wage of the entire multicampus hospital system as its appropriate wage data for reclassifications effective in FYs 2006-2008.[4]

The proposed[5] and final[6] rules published in the Federal Register regarding the adoption of this special rule discussed the possibility of permitting a campus of a multicampus hospital to submit campus-specific wage data on a manual Worksheet S-3 in a reclassification request. The final rule rejected this proposal in favor of a single campus of a multicampus hospital using multicampus data.

The Preamble to the Proposed 2007 Rule states that since only one hospital (which is Highland Park Hospital) used the special rule for multicampus hospitals and that hospital has since joined a successful FY 2007 urban county group reclassification application to the same area to which it was approved under the special rule, the special rule was no longer needed. Thus, CMS proposed not to extend the special rule beyond FY 2008. However, that successful urban county group application was dependent upon the special rule set forth in § 412.230(d)(2)(iii). Terminating the special rule places Highland Park Hospital and similar campuses of multicampus hospitals back without options to apply for reclassification.

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[3] Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, 70 FED. REG. 47278, 47444 (Aug. 12, 2005) [hereinafter, the "Final 2006 Rule"].
[4] *Id.*; *see, also*, 42 C.F.R. § 412.230(d)(2)(iii).
[5] Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, 70 FED. REG. 23306, 23436-37 (May 4, 2005) [hereinafter, the "Proposed 2006 Rule"].
[6] Final 2006 Rule, 70 FED. REG. at 47444-46.

Group Reclassifications

If, as CMS proposes, the special rule for the reclassification of a campus of a multicampus hospital is not extended, Highland Park Hospital and other hospitals would be significantly, unfairly, and adversely affected. The Proposed 2007 Rule states that because the only hospital that has used the special rule for multicampus hospitals "was able to reclassify under the normal reclassification rules," CMS believes that the special rule is no longer needed.[7] We disagree.

Without the special rule, a group of county hospitals that includes just one campus of a multicampus hospital will not have the appropriate wage data to apply for reclassification. Section 412.234(c), the regulation regarding applications for reclassification by a county group, provides that a group of hospitals seeking reclassification must submit wage data for each hospital in the group using the data that the hospitals would need to submit to apply individually. Additionally, the instructions to the group reclassification application provide that the wage data submitted must "include wages and hours for the three years used to calculate the wage index for each hospital in the group." Highland Park Hospital was only able to apply with the other Lake County hospitals because it could use the ENH wage data in accordance with § 412.230(d)(2)(iii). Lake County hospitals would not be able to satisfy this requirement with respect to Highland Park Hospital without the special rule. Thus, under the "normal reclassification rules" the MGCRB will not have the authority to reclassify the Lake County hospitals as a group in 2010 because the Lake County hospitals would be lacking the proper data for Highland Park Hospital. Thus, the original solution, which allowed Highland Park Hospital and the Lake County hospitals to apply for reclassification, would be negated, with the result that all of the affected hospitals would be disadvantaged and disqualified from applying for reclassification.

Reclassification of a Campus of a Multicampus Hospital

In general, hospitals in an urban county have the option of seeking reclassification in two separate ways: (i) in a group application and (ii) as an individual hospital. A hospital may apply under both. This is important because if for some reason the group does not qualify for reclassification, the individual hospitals may still qualify. The second option, however, would not be available to a campus of a multicampus hospital if the special rule terminates. If a campus of a multicampus hospital is in a county in which just one other hospital in the county decides not to seek reclassification, for any reason, the group application would fail and the campus would be without recourse. It would not be able to seek reclassification as an individual hospital even if it satisfied the proximity and wage criteria. Further, if for any reason the county hospitals as a group do not qualify for reclassification, the campus would likewise be unable to apply individually for reclassification. These situations would place a campus into the same situation

[7] Proposed 2007 Rule, 71 FED. REG. at 24109.

that Highland Park Hospital was in prior to the adoption of the special rule despite the fact that in either of these situations the remaining county hospitals could individually apply for reclassification, if they so desired, provided they individually met the proximity and wage criteria. This unfairly penalizes multicampus hospitals.

Although Highland Park Hospital was the only campus of a multicampus hospital to make use of § 412.230(d)(2)(iii), it is our understanding that it is not the only campus of a multicampus hospital that could have applied for reclassification. The special rule should be available for those who may need it in the future.

Additionally, if the OMB again revises its definitions pertaining to metropolitan areas, or the 2010 census changes the wage areas again, other multicampus hospitals could be affected in the same way that Highland Park Hospital was affected by the adoption of the OMB changes by CMS in 2004. Now is the time to address these issues and establish a workable solution.

Single Provider Number

The Proposed 2007 Rule states that if a campus of a multicampus hospital wants to apply for an individual reclassification, it "would have to obtain a separate provider number and be treated for Medicare purposes as an independent entity in order to provide wage data for the specific campus."[8] This would be harmful to both ENH and Highland Park Hospital, and would be more costly to Medicare.

It is of utmost importance to ENH that Highland Park Hospital remains under the ENH single provider number. It was for that reason that Highland Park Hospital pressed for a regulation that would permit it to apply for reclassification. ENH has a single governance structure, a single management structure, and fully integrated clinical departments for its three campuses. Each department has one campus-wide director. The campuses have one medical staff and each member of the medical staff is credentialed and has privileges at all three campuses.

Patients at any of the three campuses are able to benefit from services at any of the other ENH campuses and do so in fact. Inpatients at one campus frequently receive diagnostic or treatment services at one of the other campuses without the need for discharge and readmission to the other campus. Patients especially benefit from the ENH Centers of Excellence in Cardiac Electrophysiology, Acute Rehabilitation, Adult Psychiatry, and G.I. Lab, each of which is established at only one of the campuses. The inpatient wage index is also used for reimbursement for outpatient diagnostic tests and treatment at the three campuses. Again, as

[8] *Id.* at 24109.

with inpatient care, outpatients in the ENH campuses may undergo diagnostic tests and may be treated for specific ailments at more than one campus.

The campuses share a common electronic medical records system that has been nationally recognized.[9] The integrated electronic medical records system makes a patient's medical records available to treating professionals throughout the ENH system. If Highland Park Hospital is forced to obtain a new provider number, an inpatient receiving care at Highland Park Hospital and who requires treatment at either Evanston Hospital or Glenbrook Hospital or vice versa, would have to be discharged from the first campus and admitted to the second campus. Patients would lose the benefit of an integrated health delivery system. Patient records would have to be closed on discharge from the first campus and newly created on admission to the second campus, and the wealth of medical information in the first chart would not be readily available at the second campus. Outpatients would have separate medical records at each campus. The current integrated system has vastly improved patient care. At a time when a major initiative of CMS and health care professionals nationwide is to reduce barriers to clinical and financial information flow, in order to reduce time and cost, the requirement of obtaining a new provider number for a campus of a wholly integrated multicampus hospital would have the wholly unintended effect of raising costs and jeopardizing patient care.

Moreover, requiring Highland Park Hospital to obtain a new provider number would likely be more costly to the Medicare system. If a patient requires treatment at another campus, the discharging (or sending) campus would receive twice the DRG per diem for the first day of care and the per diem DRG rate for every day thereafter. The final discharging campus would receive the full DRG rate. Both campuses would be eligible to receive cost outlier payments and adjustments for direct and indirect medical education expenses for patients transferred.

These benefits to patient care and hospital efficiency make maintaining an integrated health system under one provider number critical to ENH's patients and to the ENH system. It is also important to the Medicare fisc.

Special Rule for Multicampus Hospitals

The regulation at 42 C.F.R. § 412.230(d)(2)(iii), providing a mechanism for a campus of a multicampus hospital to apply for reclassification to the metropolitan division where the hospital's other campuses are located, is a fair and appropriate rule. The reasons for using multicampus data were threefold. First, because a campus must meet proximity requirements, CMS determined that "it is reasonable to speculate that the average hourly wages for an individual campus and the whole hospital are similar because the two (or more) campuses are

[9] A representative of ENH appeared with President Bush at a Town Hall meeting in Cleveland to discuss the benefits of ENH's electronic medical records system.

operating as a single entity under one Medicare provider number, are under common ownership and control, and are clinically and financially integrated."[10] CMS speculated that salaries for each occupational category would not vary widely among the campuses. That turned out to be true in ENH's case. In compiling its application for reclassification, ENH found that the difference between average wages for the multicampus ENH system and Highland Park Hospital was negligible.

Second, CMS found that using multicampus data "is practical and administratively feasible for hospitals, CMS, and the fiscal intermediaries because wage data for all campuses are reported together on a single cost report under a single Medicare provider number."[11] Third, CMS noted that using multicampus data would be consistent with its "treatment of multicampus hospitals for calculating area wage index values, GME, DSH, and provider-based purposes, under which multicampus hospitals operating under a single Medicare provider number are treated as a single hospital for payment purposes."[12]

The reasons that CMS cited in support of using multicampus data in the Final 2006 Rule continue to support the extension or permanency of the rule.

Campus-Specific Data

As an alternative, if CMS views the use of multicampus data for reclassification of a single campus as unfair, ENH would support permitting each multicampus hospital, beginning FY 2007, to submit a supplemental Form S-3 annually with its cost report for a campus that is located in a different county. Then, once the fiscal intermediary audits that data it would be available for use by the applicable campus as official wage data. In the Proposed 2006 Rule, CMS proposed allowing a campus of a multicampus hospital to submit campus-specific wage data using a supplemental Form S-3 for purposes of the wage data required under the reclassification regulations.[13] Although this is not ENH's preferred strategy, it is workable.

In the Final 2006 Rule, CMS emphasized the burdens that would be placed on multicampus hospitals, CMS, and fiscal intermediaries in its decision not to finalize its proposal to allow a campus of a multicampus hospital to submit supplemental wage data for reclassification.[14] In addition, CMS noted the supplemental Form S-3 is linked to other worksheets and, therefore, additional worksheets would be needed for manual submission. CMS also noted that a multicampus hospital would have to separately calculate campus-specific occupational mix data. But, these burdens were related to the difficulty of hospitals compiling data, and fiscal intermediaries auditing the data, in time to meet immediate deadlines for

[10] Final 2006 Rule, 70 FED. REG. at 47445.
[11] *Id.* at 47446.
[12] *Id.*
[13] Proposed 2006 Rule, 70 FED. REG. at 23426.
[14] Final 2006 Rule, 70 FED. REG. at 47445.

MGCRB applications. CMS noted that it could make formal changes to cost reports to permit multicampus hospitals to report their wage data by campus electronically in future years but that it just was not possible for FYs 2007 or 2008.

ENH believes that the difficulties enumerated by CMS were time related. A campus of a multicampus hospital would be able to extract the required campus-specific data from the information included in its records, worksheets, and cost reports. It could submit this information on a supplemental Form S-3 in addition to providing other worksheets as appropriate. This process would be somewhat alleviated if CMS made modifications to the electronic cost report. Either way, any administrative burden imposed on hospitals, CMS, and fiscal intermediaries would be far less than those that would be imposed if a campus were forced to obtain a separate provider number. This would force the hospital to create, and the fiscal intermediate to audit, an entire cost report rather than just one or two schedules.

If CMS implements a supplemental Form S-3, the special rule in § 412.230(d)(2)(iii) should be extended for MGCRB reclassification applications through at least fiscal year 2012. Because the wage data that is used for geographic reclassification precedes the payment year by five years, applications filed by September 1, 2012 for fiscal year 2013 would be the earliest applications for which a campus would be able to provide the necessary campus-specific information.

Conclusion

Multicampus hospitals located in two or more counties, their individual campuses, and their patients would be unnecessarily and adversely impacted if § 412.230(d)(2)(iii), the special rule for multicampus hospitals, is not extended. Evanston Northwestern Healthcare strongly urges CMS to extend or make permanent the special rule for multicampus hospitals. In the alternative, ENH urges CMS to extend the special rule in § 412.230(d)(2)(iii) until FY 2012 and adopt a new regulation permitting a campus of a multicampus hospital to submit supplemental campus-specific data on a supplemental Form S-3 or similar document for purposes of reclassification.

Sincerely,

Marion Kristal Goldberg

180


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June 9, 2006

Attention: CMS-1488-P

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RE: CMS-1488-P: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates

Dear Dr. McClellan:

On behalf of the American College of Emergency Physicians (ACEP), I am pleased to submit comments on the proposed rule for the Hospital Inpatient Prospective Payment System for Fiscal Year 2007, published in the Federal Register on April 25, 2006. ACEP is a national medical specialty society with more than 23,000 members, dedicated to improving the quality of emergency care through continuing medical education, research, and public education. We appreciate the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with our comments on inpatient hospital payment policy and its effects on the delivery of emergency medicine services.

ACEP's comments will focus on proposed changes/clarifications to EMTALA and graduate medical education (GME) policy.

EMTALA

ACEP is pleased to support the two proposals in the draft rule that clarify concerns about certification of labor (childbirth) and hospital specialized capabilities. These two recommendations came from the EMTALA Technical Advisory Group whose members are in the process of analyzing current EMTALA statutory, regulatory, and interpretative guideline language. It is our observation that TAG members have endeavored to make practical and sound policy recommendations to a law whose interpretation and enforcement has had many unintended consequences over the past 20 years of its existence.

The first recommendation allows a certified nurse-midwife or other hospital-designated qualified medical person acting within his/her scope of practice and in accordance with hospital policy to certify that a woman is in "false labor." Previously, only a physician was permitted to make the determination of false labor. This requirement resulted in needless delays after a woman would go straight to the labor and delivery unit, be seen by an obstetric nurse, and then have to wait until an emergency or other physician could verify the findings of the obstetric nurse.

The second recommendation clarifies that the statutory language describing "specialized capabilities" applies to limited service/specialty hospitals. Specifically, patients in an emergency department can be transferred to a specialty hospital that has the medical capabilities needed by the patient, e.g. cardiac, orthopedic, psychiatric, whether or not the receiving hospital has a dedicated emergency department. We agree with CMS' interpretation of the statute. We do, however, continue to have grave concerns about the availability of psychiatric resources in the community, a problem exacerbated by the bar on Medicaid reimbursement to private psychiatric hospitals. These patients often spend hours, even days boarding in the nation's emergency departments while emergency physicians and hospital staff scramble to find inpatient psychiatric accommodations.

Graduate Medical Education

CMS reiterates what is described as longstanding policy of paying hospitals only for the time residents spend related to patient care. The time residents spend on education such as lectures, journal clubs, conferences, and seminars would be excluded from the teaching hospitals' FTE resident count if the training took place outside of the hospital "complex".

ACEP strongly supports an interpretation of the regulations that the costs "related to patient care" should include all types of resident training, not just hands on patient care. Given the extraordinary amount of resources CMS has put into patient quality and safety initiatives, it seems counterintuitive to disallow payment for residents to participate in educational activities designed to teach young clinicians how to incorporate safety and quality activities into their practices. For example, residency training that takes place in the anatomy lab/animal lab of the medical school is crucial to practicing difficult procedures before performing them on patients. Further, this interpretation discriminates against smaller teaching hospitals that may not have the space or resources to conduct certain types of educational sessions within their complexes. These aspects of medical training are integral to quality patient care, and should be recognized as legitimate GME costs under the Medicare program.

Documentation of FTE Residents

CMS' current regulations state that a teaching hospital may count resident FTE time for payment purposes while they train in non-hospital sites, but not when they train in other hospitals, regardless of whether the teaching hospital incurs all of the training costs. For obvious reasons, emergency medicine residents train in hospitals and this policy provides a tremendous disincentive to expand training to rural hospitals.

Emergency medicine is a relatively young but growing specialty that is very popular with graduating medical students. For the past several years, close to 95 percent of the emergency resident slots have been filled through the annual match program. As we pointed out to CMS staff during our discussions of Sec. 422 of the MMA 2003, Accreditation Council for Graduate Medical Education rules require a certain volume of cases for residency training, and consequently there are no rural training programs. At the same time, there is a tremendous need for residency trained, board-certified emergency physicians in rural areas. Emergency physicians are trained to treat a large number of illnesses and traumatic injuries using state of the art approaches while many local (non-emergency) physicians who cover rural emergency departments have not received the same level of training. The need for physicians with advanced life saving skills has increased

greatly over the past few years as fewer and fewer specialists are willing to take call in emergency departments which limits patient access to advanced levels of care.

Emergency medicine residency programs have attempted to expand rotations to rural hospitals to expose residents to rural practice where they are sorely needed when they graduate. The current policy is antithetical to long standing efforts of CMS, HRSA, and other government agencies to improve geographic distribution of physicians as emergency medicine graduates will not likely consider rural practice opportunities if they have not had experience with rural emergency medicine in residency.

As a practical matter, few small rural hospitals that serve as sites for emergency resident rotations want to undertake the burden of becoming teaching hospitals in their own right, so the main teaching hospital continues to pay the costs of the residents who rotate to rural institutions. Our residency program directors state that many more teaching hospitals would make rural training available if the primary teaching hospital was reimbursed for the costs incurred while residents rotate to rural hospitals.

We urge CMS to change this policy for emergency and possibly for other hospital-based physicians and allow payment to the main teaching institution for resident time spent at rural hospital rotations in cases where the rural hospital has concluded that becoming a teaching hospital for Medicare purposes is not economically feasible. This change could significantly increase the number of residents who choose rural hospital practice.

We appreciate the opportunity to offer these comments, and we look forward to continuing to work cooperatively with CMS in order to address these important issues. If you have any questions about our comments and recommendations, please contact Barbara Marone, ACEP's Federal Affairs Director at (202) 728-0610, ext. 3017.

Sincerely,

Frederick C. Blum

Frederick C. Blum, MD, FACEP, FAAP
President

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June 9, 2006

Mark McClellan, M.D., Ph.D.
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Washington, DC 20201

RE: Proposed Changes to Hospital Inpatient Prospective Payment Systems, FY 2007 (CMS-1488-P)

Dear Dr. McClellan:

On behalf of Johnson & Johnson, I am pleased to submit comments and recommendations in response to the Proposed Changes to Hospital Prospective Payment Systems, FY 2007, issued in the Federal Register by the Centers for Medicare & Medicaid Services (CMS) on April 25, 2006. This letter summarizes our recommendations in response to the proposed rule, and the first attachment to this letter discusses our comments in detail.

Johnson & Johnson (J&J) is the world's most comprehensive and broadly-based manufacturer of health care products for the consumer, pharmaceutical and medical devices and diagnostics markets. For 120 years, J&J has supplied hospitals with a broad range of products and has led the way in innovation; from the first antiseptic bandages and sutures to the first drug-eluting stents. The consistent fundamental objective of J&J is to provide scientifically sound, high quality products and services to help heal, cure disease and improve the quality of life.

In that regard, our greatest concern with this proposed rule is the threat that it poses for patients' access to the latest medical advances. Taken together, the proposed changes represent a fundamental and disturbing shift away from Medicare's current and past efforts to ensure full access to advanced medical technology for beneficiaries. The proposals particularly harm academic medical centers that lead the way in technology adoption and development. First, the proposed methodology would remove all cost variation across hospitals from the calculation of the diagnosis-related group (DRG) weights, without fully analyzing or understanding the reasons why some hospitals may have higher average costs than others (even after adjusting for patient mix). Second, the proposed methodology estimates costs using average cost-to-charge ratios that ignore the variations across hospitals in patient volume, thereby skewing the results toward smaller hospitals and negatively impacting large hospitals. Third, CMS proposes a severity-

adjusted DRG system that would roll back the clock on past policy decisions recognizing the higher costs of beneficial medical technologies that are already in widespread use

We support efforts to improve the accuracy of the DRG weights, and better reflect variations in patients' severity of illness. However, we believe the proposal is flawed from both a methodological and policy perspective, and should be delayed to allow more complete consideration before such sweeping changes are implemented. In our opinion, the proposal, if implemented, would unnecessarily disrupt current positive trends that reflect medical advances that enable less invasive patient care.

SUMMARY OF RECOMMENDATIONS

1. Withdraw the methodologically flawed proposal for 2007 and use the current standardized charge-based approach.
As detailed in our attached comments, there are several methodological flaws in CMS' proposed methodology that must be corrected in order to maintain the overall integrity of the DRG system. Correcting these flaws significantly affects the payment impacts of the change, and therefore, at a minimum, it is necessary to publish a corrected methodology for public comment prior to implementation.

2. Delay implementation of the hospital-specific relative value methodology at least until further analysis is conducted of the impacts and interactions with cost-based weights.
Hospital-specific relative values (HSRV) eliminate the effects of all cost variation between hospitals, without regard to whether the costs are legitimate or otherwise compensated through the payment system. Currently, CMS standardizes hospitals' charges to remove variation due to identifiable factors such as geographic variation in labor costs and treating a disproportionate share of low income patients, but does not remove the effects of other unidentified costs. Especially prior to implementation of a refined severity DRG system, some of the costs being removed are likely due to patient severity that is unexplained by the current DRG system.

In addition, the attachment describes past research that found the HSRV method has a significant negative impact on hospitals that perform above average numbers of cardiac surgical or interventional procedures, due to cross-subsidization through hospitals' internal charging practices. This raises questions about the interactions of the HSRV methodology and cost-based weights, which also adjusts for variations in charging practices. This issue needs to be fully explored and understood before proceeding with a combination of HSRV and cost-based weights.

3. Abandon national average cost-to-charge ratios (CCRs) and instead use hospital-specific CCRs as are currently used for the outpatient prospective payment system (OPPS).
CMS believes that using national average rather than hospital-specific CCRs enables it to use claims data from a different year than the cost report data. However, it is not readily

apparent that the same objective could not be achieved using hospital-specific CCRs. In fact, as outlined in the attachment to this comment letter, we believe this would be more accurate (because it matches CCRs with charges relative to hospitals that actually perform each DRG) and administratively simpler (because it avoids the step of calculating national averages) than either the proposed national average CCR methodology or a corrected version.

4. The cost reports are inadequate to support an accurate cost-based DRG system. While we support the concept of cost-based DRGs, we are concerned the cost report information necessary to accurately support this system is not currently available. For example, charge compression is an ongoing concern under the OPPS. Although charge compression also biases the charge-based DRG weights downward, the downward bias on device-intensive DRGs would be much more significant under cost-based DRG weights. Similarly, past research has shown the cost reports overestimate routine area costs and underestimate ancillary costs. These combined effects have the potential to cause cost-based DRG weights to systematically underpay for technologies that have the potential to reduce patient stays through less invasive procedures.

Therefore, we are recommending that CMS commission an expert panel to explore ways to better capture the information needed to support a cost-based DRG system. Ultimately this effort should identify changes to the cost reports that reduce the net information burden on hospitals, while improving overall payment accuracy. An example may be a separate cost center for implantable devices. The panel would report its recommendations by April 2007.

We also support further development of recent analysis to identify a potential adjustment for charge compression using more specific revenue center codes than are available from the cost reports. This analysis is described in some detail in AdvaMed's comments on this proposed rule. We believe this analysis could potentially support an adjustment if cost-based DRG weights are adopted in 2008.

5. We support implementing severity-adjusted DRGs that better reflect the resources hospitals use to treat different types of patients, but CMS' proposed system is seriously flawed because it eliminates numerous existing DRGs that recognize the higher costs of some medical technologies.
We believe a starting point for any severity-adjusted DRG system that CMS would adopt is that it incorporates the current DRGs that CMS has already created to recognize additional costs of medical technology. CMS has indicated its interest in incorporating case complexity into severity-adjusted DRGs. The place to start in this effort would be to split the current base CMS DRGs into severity levels, rather than using 3M's APR-DRGs.

6. We support the position that severity-adjusted DRGs must be implemented at the same time as the other changes to avoid a whip-sawing effect on hospital payments from one year to the next.

This should be done no sooner than in FY 2008.We also believe that, like many previous major changes to the inpatient prospective payment systems, any eventual change to the DRG weighting methodology should be phased-in over a multiple year transition schedule.

7. We applaud the Administration's efforts to improve patients' access to information about the care they receive.

The proposed rule also discusses the Administration's interest in greater transparency of health care information, including charge and pricing data. We urge CMS to integrate pricing and quality information on appropriate evidence-based protocols. Patients need to know both the costs and benefits of the care they receive, in a format that is understandable and accessible. We also urge CMS to consider appropriate timeframes for measuring quality and costs, and to look across all sites of care delivery to assess efficiency.

J&J appreciates the opportunity to submit our comments and recommendations to CMS. We look forward to working with you and your staff to ensure the accuracy and fairness of Medicare's payments to hospitals.

Sincerely,

Kathleen A. Buto

Attachments: 2

Attachment 1: Johnson & Johnson's Comment Letter On CMS-1488-P

Hospital-Specific Relative Value (HSRV) Weights

As noted in the proposed rule, last year the Medicare Payment Advisory Commission (MedPAC) recommended changes to the DRG weight calculations out of concern that the charge-based weights have introduced bias into the calculation due to differential charge mark-ups for ancillary services among the DRGs. MedPAC's analysis concluded that, as a result of this bias, some DRGs are much more profitable than others, potentially giving rise to hospitals that specialize in those profitable DRGs.

CMS has proposed to adopt two of the approaches to calculating the DRG weights MedPAC proposed for 2007, with modifications in the methodology. First, CMS proposes to adopt the HSRV methodology. Second, CMS proposes to use cost-based weights rather than charge-based weights, although the methodology is substantially different from MedPAC's approach. Additionally, CMS has proposed to adopt patient severity-based DRGs beginning in 2008 or earlier, although it indicates it will consider an alternative implementation schedule for all of these changes. Our comments on this proposal are in a later section.

Although we support efforts to improve the payment accuracy of the DRGs to ensure hospitals are fully and fairly compensated for the services they provide, we have a number of concerns with the specifics of CMS' HSRV cost center (HSRVcc) methodology. We also have broader concerns about the HSRV methodology and cost-based DRG weights, and these concerns are described below.

HSRVcc Methodology Issues

CMS proposes an administratively simpler methodology than the one MedPAC used. According to CMS, this simpler approach facilitates annual updating of cost-based DRG weights. We support CMS' efforts to ensure the DRG weights are updated annually to reflect the most recent trends in inpatient care. It is essential that any DRG recalibration methodology use the most recently available claims data in order to adequately reflect new technology.

However, we believe there are methodological flaws as well as policy concerns associated with the HSRVcc methodology as proposed. In proposing this approach CMS stated its belief that it achieves similar results to the MedPAC methodology. We disagree with this conclusion based on the following analysis. Furthermore, even if these flaws are corrected, the resulting impacts on hospitals would be so different from those shown in CMS' proposed rule that there would not be an opportunity for the careful consideration that is warranted by such a monumental change in the DRG system.

Unweighted Means In the proposed rule, CMS uses national geometric mean CCRs for each of 10 cost centers. These means are unweighted and therefore do not account for the varying amount of Medicare charges each hospital contributes to total charges. As a

result, very small hospitals individually have just as much impact on the mean CCRs as larger hospitals. Mathematically, the only correct way to get from total hospital charges to total hospital costs is to use a charge-weighted average of the hospital CCRs.[1] Therefore, applying these unweighted ratios to charges does not produce an accurate estimate of the national average cost per case.

We are not aware of a similar calculation in Medicare's payment systems that weights providers equally regardless of their case volume. Using unweighted CCRs in the calculation to arrive at cost-based DRG weights raises questions about the consistency of the DRG weights with other aspects of the inpatient prospective payment system that have been calculated by weighting based on case volume, such as the standardized amounts, the indirect medical adjustment factor, and the adjustment for treating a disproportionate share of low-income patients.

We are also concerned that using national mean CCRs that are not weighted for charges has the potential to introduce instability into the DRG relative weights. Because small hospitals contribute to the calculation as much as large hospitals with many more charges, there is the potential that the mean CCRs could be disproportionately affected from one year to the next by the greater rate of closure or consolidation among small hospitals (or by these hospitals becoming critical access hospitals).

Trimming Routine Care CCRs CMS trimmed the cost center CCR calculation at 1.96 standard deviations from the geometric mean. That systematically excluded hospitals with high markups on routine accommodation charges from the CCR calculation. On net, the CMS trim excluded 238 large hospitals that together accounted for 25 percent of total routine accommodation charges. However, the CCRs for these hospitals appear to be predominantly correct. In addition, the charges for these hospitals are included in calculating the cost center DRG weights despite them being excluded from the calculation of the average CCR. The result is a significant mismatch between the CCRs and the pool of charges to which they are applied.

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[1] Let H subscript hospitals, let Σ_H mean the sum across all hospitals, let Charges be the charges for routine days, and let Cost be the cost for routine days. Then:

- Cost at a hospital is charges times that hospital's CCR:
  $Cost_{(H)} = Charges_{(H)} * CCR_{(H)}$
- Total US cost or total US charges is the sum of that, across all hospitals:
  $Cost_{(US)} = \Sigma_H\{Cost_{(H)}\}$
  $Charges_{(US)} = \Sigma_H\{Charges_{(H)}\}$
- Substitute Charges x CCR for cost (algebra)
  $Cost_{(US)} = \Sigma_H\{ Cost_{(H)} \}$
  $Cost_{(US)} = \Sigma_H\{Charges_{(H)} * CCR_{(H)}\}$
- Multiply by 1, in the form of total US charges divided by total US charges.
  $Cost_{(US)} = [1] * \Sigma_H\{Charges_{(H)} * CCR_{(H)}\}$
  $Cost_{(US)} = [\Sigma_H\{Charges_{(H)}\} / \Sigma_H\{Charges_{(H)}\}] * \Sigma_H\{Charges_{(H)} * CCR_{(H)}\}$
- Re-arrange the terms (commutative law)
  $Cost_{(US)} = \Sigma_H\{Charges_{(H)}\} * [\Sigma_H\{Charges_{(H)} * CCR_{(H)}\} / \Sigma_H\{Charges_{(H)}\}]$

The term on the far right is the definition of the charge-weighted cost-to-charge ratio.

These CCR issues (unweighted means and excessive trimming of the data) are not minor technical errors, but rather they are significant methodological flaws with significant impacts on the analysis presented in the proposed rule. Where CMS estimates a routine accommodation CCR of 0.85, the charge-weighted, charge-trimmed, CCR is 0.55. Similarly, CMS calculated the intensive care CCR to be 0.72, while the charge-weighted, charge-trimmed CCR is 0.48. This affects the cost shares used to calculate the final DRG weights, overweighting routine and intensive care unit costs relative to ancillary costs, and grossly exaggerating the impact of a shift from standardized-charge DRG weights to cost-based DRG weights. The DRG weight changes in the CMS proposed rule are typically two to three times larger than the changes that would have occurred if correct CCRs had been used, and leaving the rest of the proposed methodology unchanged.

The following table illustrates the dramatic effects of these combined flaws. This table shows the average payment impacts of the proposed DRG changes on DRGs within major diagnostic category (MDC) 19, Mental Diseases and Disorders, and DRGs within MDC 5, Diseases and Disorders of the Circulatory System. The table shows that correcting the errors reduces the impact on MDC 19 due to the high proportion of routine area charges in these DRGs, and also reduces the negative impact on MDC 5, due to the high proportion of ancillary charges in these DRGs.

MDC	Title	Impact of Proposed Rule	Impact After Correcting Errors
5	Diseases and Disorders of the Circulatory System	-16%	-9%
19	Mental Diseases and Disorders	64%	46%

A simple way to understand the impacts of these errors is to compare total cost to total payment using the CMS CCRs. Even after adjusting for charge inflation between the 2003 cost reports and the 2005 claims, estimated costs per case using the CMS CCRs are at least 20 percent higher than Medicare's average payment per case. This suggests that either CMS' cost estimate methodology is seriously flawed or Medicare is paying hospitals well below costs. If indeed CMS were paying hospitals at only 80 percent of costs, the repercussions for Medicare patients would be massive. Therefore, it seems much more likely that CMS' proposed methodology is seriously flawed.

Moreover, the impact varies across DRGs depending on the proportion of routine or intensive care charges in the DRG, causing distortions in the relative weights and creating major disincentives for certain forms of treatment. By overestimating routine costs relative to ancillary costs, the proposal would actually create incentives favoring DRGs with longer lengths of stay relative to DRGs where higher ancillary costs are incurred but length of stay is reduced.

Impacts Misleading as Published Moreover, correcting these errors significantly affects the hospital impacts as displayed in the proposed rule, resulting in misleading conclusions about the effects of the proposed policies. For example, the proposed rule

suggests that rural hospitals would benefit by 3.0 percent from adopting the HSRVcc methodology (Table I, page 24407). If these errors were corrected, the positive impact on rural hospitals would be approximately 1.6 percent.

Consequently, we believe CMS must provide a full notice and comment period after correcting the errors noted above in order to allow hospitals and other stakeholders sufficient opportunity to evaluate this proposal. Such a change to the DRG weight calculation, the core of Medicare's payment for inpatient services, is much too significant to implement without a completely transparent and thorough evaluation by all interested parties.

National Average CCRs for 10 Cost Centers MedPAC's analysis matched claims data with the dates covered on the latest available cost reports. Because claims data are available sooner than cost report data, this approach necessitates using older claims data than are actually available. This would mean an even longer delay before data reflecting new medical technologies are used to establish DRG weights.

We acknowledge CMS' goal to minimize the administrative complexity of cost-based weights, and we fully support CMS' commitment to using the most recently available claims data in the DRG recalibration methodology. This at least ensures the most recent medical technology is reflected in the charge data. However, we have the following comments about several aspects of the proposal to use national average CCRs rather than hospital-specific CCRs.

We understand that CMS believes that using national average rather than hospital-specific CCRs enables it to use claims data from a different year than the cost report data. However, it is not readily apparent that the same objective could not be achieved using hospital-specific CCRs. In fact, we believe this would be more accurate (and administratively simpler) than either the proposed HSRVcc methodology or a corrected version with charge-weighted average CCRs.

Using hospital-specific CCRs would not require weighting and would incorporate data only for hospitals that actually perform specific DRGs. Notably, this is the approach CMS uses to establish payment rates under its outpatient prospective payment system (adjusting the most recently available claims data by prior years' hospital-specific CCRs).

In the proposed rule, CMS said the hospital-specific approach used by MedPAC required detailed cost center distinctions for each hospital that would require using the Standard Analytical File (SAF). According to CMS, using the SAF "increases processing time and adds further complexity to the process of setting the relative weights" (p. 24007). However, according to the record layout description for CMS' Medicare Provider Analysis and Review (MedPAR) file, the file CMS currently uses to set the charge-based DRG weights, MedPAR does include detailed charge information by cost center. Therefore, it is not apparent why CMS would be required to use the SAF if it were to adopt hospital-specific CCRs in a cost-based DRG methodology.

CMS also expressed concern that using hospital-specific CCRs would result in more data being excluded due to missing CCRs. However, no analysis is presented to indicate the extent to which this missing data may bias the calculation (i.e., relative to using national average CCRs that include hospitals that may not perform a particular DRG). Furthermore, to the extent this is a problem it could be resolved by using national average CCRs only for hospitals with missing CCRs.

HSRV Policy Issues

MedPAC recommended HSRV weights as a way to remove the effects of differences in hospitals' overall cost levels on the DRG weights. Currently, CMS standardizes hospitals' charges to remove variation due to factors that are otherwise recognized through the payment system, such as geographic variation in labor costs and treating a disproportionate share of low income patients. All other sources of variation across hospitals remain. However, using the HSRV methodology eliminates the effects of all cost variation between hospitals, regardless of the source or whether it is related to patient care (but not accounted for due to limitations in the patient classification system).

CMS notes "it is evident to us that some hospital types (for example, teaching hospitals) are systematically more expensive overall than the average hospital and certain case types are more commonly treated at these more expensive facilities. This fact results in an upward bias in the weights for these types of cases (page 24007)." We believe it is incumbent on CMS to better understand the sources for this variation prior to taking the position that none of it should be reflected in the DRG weights. Teaching hospitals in particular treat patients that are referred by other hospitals that are unable to provide the necessary specialized care. Eliminating all cost variation between teaching and nonteaching hospitals may, in fact, eliminate legitimate cost differences that are appropriately included in the current DRG weights. This would be especially problematic if CMS were to implement HSRV weights without adopting severity-adjusted DRGs, as proposed.

Furthermore, it is questionable whether it is necessary or appropriate to combine the HSRV methodology with cost-based weights. Analysis by RAND researcher Grace Carter found that "hospitals that lose under HSRV charge more than expected for their typical cases but not for their expensive cardiac surgery cases is consistent with these hospitals subsidizing very expensive services with excess revenue from less expensive services."[2] In other words, to the extent hospitals differ in how they mark-up charges across cost centers, the HSRV and cost-based weights both adjust for this effect.

Neither MedPAC nor CMS addressed this interaction of the HSRV methodology and cost-based weights. Specifically, both methodologies remove the effects of differential charge mark-ups. Therefore, it is unclear whether the two methodologies work independently to remove effects not adjusted by the other, or whether there is

[2] Carter, G., "How Recalibration Method, Pricing, and Coding Affect DRG Weights – Diagnosis-Related Groups," Health Care Financing Review, Winter 1992 (accessed May 2006 at: http://www.findarticles.com/p/articles/mi_m0795/is_n2_v14/ai_13275193/print).

inappropriate overlap between the two resulting in double-removal of the same differential mark-ups by both methodologies. To ensure the transparency and accuracy of the changes, this issue needs to be fully explored and understood before the two methodologies are adopted together.

Cost-Based Weights Policy Issues

Concern that different charge mark-ups across cost centers within hospitals (e.g., higher mark-ups in ancillary areas compared to routine areas) cause distortion in the DRG weights led MedPAC to recommend cost-based weights. At a conceptual level, cost-based weights should better reflect the actual resources hospitals employ to provide inpatient care. As noted previously, charge compression for costly medical devices is a current source of inaccuracy in the payment system.

However, because the claims submitted by hospitals currently reflect charges and not costs, the accuracy of cost-based weights is dependent on the data available to adjust charges to costs, specifically the CCRs. Research has shown that CCRs are inaccurate estimators of costs at the individual cost center level. Unfortunately, the problem of charge compression is compounded when using the current cost center CCRs to estimate costs.

One problem when trying to estimate costs by applying CCRs to charges on a claim is that this approach has been shown to overestimate routine area charges. One study found that routine and special care cost estimates for Medicare patients using this approach were overstated by more than 12 percent.[3] This finding was attributed to the use of a single routine area CCR for all patients despite the fact that pediatric patients "are significantly more expensive to treat on average than the average aged patients who comprise the vast majority of the Medicare population."

This same study found that using ancillary cost center CCRs resulted in underestimating ancillary costs for Medicare patients by nearly 5 percent. The study concludes that, while the cost reports are reasonably reliable for determining Medicare's share of total costs, "(t)he cost report's reliability is reduced considerably when routine inpatient costs and ancillary costs are analyzed separately. And cost report data, supplemented by charge data from the MedPAR system, are clearly not reliable or accurate for analyzing micro-level costs."

Unfortunately, no more recent analysis has been done to either confirm or refute that conclusion. This draws into question not only the significant shift in payments from surgical DRGs to medical DRGs resulting from CMS' proposal, but it also raises questions about MedPAC's conclusion that many cardiac DRGs are overpaid relative to their costs. Because MedPAC estimated costs using the same methodology that was applied in the study, it is likely the analysis underestimated the ancillary costs for cardiac DRGs, causing them to appear to have lower costs than they actually do.

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[3] Ashby, J, "The Accuracy of Cost Measures Derived From Medicare Cost Report Data", Prospective Payment Assessment Commission, Intramural Report I-93-01, March 1993.

In fact, using hospital-wide CCRs (those currently used by Medicare to determine whether hospitals qualify for outlier payments) indicates much smaller adjustments are appropriate to the DRG weights in MDC 5 than indicated by MedPAC's analysis. Interestingly, the study referenced above found that hospital-wide CCRs appeared to produce better estimates of actual costs (comparing with their internal "state-of-the-art" accounting systems) than using cost center CCRs.

The policy issues associated with this overestimation of routine costs and underestimation of ancillary costs are significant, especially when it comes to the incentives to use medical technology to find new ways to discharge patients sooner with less trauma. Overpaying DRGs with a greater proportion of routine costs relative to DRGs with relatively few routine costs (and more ancillary costs), as CMS' proposal would do, will cause hospitals to under invest in new medical technologies because they would be systematically underfunded by Medicare.

In addition to this overestimation of routine costs and underestimation of ancillary costs, there are other problems with the cost report that would need to be addressed under a cost-based DRG weighting approach. One is the inconsistency in how hospitals report medical devices and other items on their cost reports. For example, one hospital may assign drug-eluting stents to the cardiology cost center, while another hospital may assign them to medical supplies and equipment. This is one reason why, as discussed above, hospital-specific cost center CCRs would be more accurate than national average CCRs.

Another well-documented issue with using cost center CCRs is the below-average mark-up of charges for expensive medical devices (charge compression). Changing to cost-based weights using cost center CCRs would underestimate the costs of these devices because the average CCR for the cost center would be less than the CCRs for these individual devices. The impact of charge compression would be made even worse under the proposal, because the national average CCRs for all hospitals are often lower than the average CCRs among hospitals actually performing a procedure.

Charge compression is already a significant source of underpayment under Medicare's outpatient prospective payment system. It also depresses the DRG weights currently for those DRGs where the charges would otherwise be higher. Moving to cost-based DRG weights without accounting for charge compression would make this payment distortion much more acute. Combined with the problem described previously where using cost center CCRs has been shown to overestimate routine costs and underestimate ancillary costs, we have great concerns that, rather than achieve the desired goal of improving payment accuracy, the proposed cost-based methodology will create barriers to the introduction of new technologies and even reverse positive trends already underway (e.g., increased use of coronary artery stenting in place of coronary bypass graft surgery).

The problem of charge compression is compounded by the age of the cost report data used to adjust the charges to costs. Although CMS used the most recently available cost reports it had, those cost reports began during Federal fiscal year 2003. Much of these data are over 3 years old. As we have stated above, we applaud CMS for its proposal to

use the most recent claims data rather than matching old claims to cost reports. This does at least ensure the charge data reflect new technologies. However, adjusting these charges using CCRs that do not reflect the lower mark-ups hospitals generally apply to these new technologies compounds the problem of charge compression (i.e., drug-eluting stents only came onto the market at the end of April of 2003, with relatively slow uptake in the latter half of FY 2003).

The example below demonstrates how the combination of charge compression and the lag time for cost report data create a disincentive for hospitals to adopt a new technology. The example demonstrates using cost report data result in a lower cost estimate (and correspondingly lower DRG payments) when a new technology is adopted, even under a scenario where total charges are unchanged (due to higher ancillary costs from the new technology).

While total charges stay the same after introducing the new technology (resulting in no payment change under the current charge-based method), applying the historical CCRs from the cost report results in a reduced estimate of costs. This is because these historical CCRs for the cost center do not reflect the lower charge mark-up for the new technology. The new methodology could, therefore, offer an incentive to the hospital to maintain the older treatment given it would have a higher "cost-based" payment rate.

Patient Treated with High Concentration of Routine Services and Long Length of Stay

	Charges
Routine Services (85% CCR)	$15,000
Ancillary Services (34% CCR)	$5,000
Total Charges	$20,000
Estimated Costs Based on Proposed CCR	**$14,450**

Patient Treated with High Concentration of Ancillary Services (Supplies & Equipment) with Shorter Length of Stay

	Charges
Routine Services (85% CCR)	$5,000
Ancillary Services (34% CCR)	$15,000
Total Charges	$20,000
Estimated Costs Based on Proposed CCRs	**$9,350**

We support further development of the analysis discussed in AdvaMed's comments regarding a potential regression-based adjustment for charge compression. We agree the analysis provides a solid analytical basis for an adjustment, and hope that CMS pursues this approach. However, we would emphasize that this adjustment should be part of a

comprehensive approach to improve the payment accuracy of the DRGs no sooner than in 2008. We believe this adjustment needs to be further analyzed. In particular, we would note that it is limited in its ability to estimate charge compression associated with drug-eluting stents by the fact that the analysis to date relies on 2003 cost report data. As explained above, there would be very little data reflecting this now widespread technology in the 2003 cost reports. Nonetheless, the analysis represents a significant step toward addressing the problem of charge compression (perhaps in conjunction with developing separate cost centers on the cost report for high-cost implantables).

Finally, we would support the use of an expert panel representing all stakeholders and commissioned by CMS (within the constraints of the Federal Advisory Committee Act) to provide advice on long-term solutions to issues and providing up-to-date cost data, either through the cost reports or other means, in support of cost-based weights. We believe the problems addressed above are real and merit immediate attention prior to proceeding with cost-based weights. If such a panel were commissioned, we believe it would be reasonable to expect a report back by Spring 2007 with specific recommendations. J&J would be pleased to assist with this panel.

DRGs: Severity of Illness

CMS proposes to adopt DRGs that better reflect differences in patients' severity of illness for FY 2008, although the proposed rule also discusses and solicits comments on the option of implementing severity DRGs in 2007. The severity-adjusted DRG system described in the rule is based on 3M Health Information Systems' APR-DRGs. However, CMS would consolidate severity level 4 from all APR-DRGs within each MDC to create a single severity level 4 DRG for each MDC (with some specific, limited exceptions described in the proposed rule).

CMS provides several reasons for why it did not propose to implement what it terms 'consolidated severity-adjusted DRGs' for 2007. Chief among the reasons cited were the limited time available for hospitals to review and adopt the major changes to the coding system represented by the consolidated severity-adjusted DRGs. We support CMS' position that this is a major change to the central structure of Medicare's inpatient payment system and it is crucial that it be fully understood. Our comments below detail a number of specific areas where we think the system described in the proposed rule needs further development.

Before addressing specific concerns about the proposed severity DRG system, we would like to register our disagreement with the phased implementation of HSRV, cost-based weights, and the severity DRG system. Because the payment impacts under cost-based and HSRV weights move in different directions than under severity-adjusted DRGs for some hospitals, implementing these changes in different years would cause unnecessary payment disruptions. For example, major teaching hospitals experience a negative 1.1 percent impact from implementing HSRVcc, but a positive 0.5 percent impact from implementing consolidated severity-adjusted DRGs. Major teaching hospitals also treat large numbers of uninsured patients every year so that it is already difficult to finance

their operations. Implementing these changes to the DRGs at the same time would help to smooth out the potential negative implications on these critical safety net providers.

Consistent with our support for improving the overall accuracy of the DRG system stated above, J&J supports improving the ability of the system to differentiate between patients of varying severity. Therefore, we appreciate that CMS is describing its proposal now to allow full consideration and comment for 2008. However, because CMS did raise the possibility of implementing this system in 2007, we would like to state our emphatic objection to this idea. We believe the reasons CMS gave in the proposed rule for not implementing this year are valid. They are all the more valid because hospitals now would have even less time to prepare if CMS were to implement its proposed severity adjusted DRG this October 1. Finally, we do not believe the system as proposed is ready for implementation.

The APR-DRGs include 314 base DRGs (each divided into 4 severity categories) while the current CMS DRGs include 367 base DRGs and 526 total (e.g., reflecting split DRGs for patients with/without comorbidities and complications). In many cases, these discrepancies reflect the fact that the current CMS DRGs reflect differences in the complexity of patients apart from their severity of illness. The proposed rule points out that under the current CMS DRGs there are different DRGs for coronary angioplasty with and without the insertion of a stent. The current APR-DRGs do not make this distinction. Because the proposed consolidated severity-adjusted DRGs use the APR-DRG base DRGs, this system would not distinguish between angioplasty with or without stenting (or the insertion of a drug eluting stent rather than a bare metal stent, a distinction that is also recognized by the current DRG system).

We strongly object to the proposed consolidated severity-adjusted DRG system because it does not recognize differences in patient complexity. CMS has examined many of these issues in great detail in the past and has adopted the CMS DRGs to reflect differences in case complexity. The proposed rule would undo many of those past policy decisions that have been implemented through notice and comment rulemaking without even acknowledging this impact (see Attachment 2 to our comments for illustrative examples). Because many of these decisions have recognized the utilization of innovative medical technologies in the CMS DRGs, this proposed severity system, combined with the flaws in the HSRVcc, would reverse the current positive trends toward more effective and less invasive patient care as a result of the introduction of new technology.

Rather than revisiting past policy decisions, CMS should develop and propose a system that establishes severity adjustments for the current CMS based DRGs (after eliminating the current CC/no-CC splits), including all of those CMS DRGs that reflect complexity of treatment or increased costs for new technologies. We note that CMS indicated in the proposed rule that "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system." A good first step would be to continue to recognize those technologies that are already recognized under the DRG system.

The proposed rule indicates that CMS plans to "develop criteria for when it is appropriate to recognize increased complexity in the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments" (p. 24014). As a worldwide leader in the development of innovative medical technologies, J&J is keenly interested in this issue. Unfortunately, the scope of the proposed DRG changes and the many issues raised above make it impossible to conduct the analysis necessary to appropriately consider this issue during the current comment period. However, we would be eager to work with CMS on this issue.

Finally, CMS requested comments on whether it should implement the DRG changes in a phased transition. We believe it would be necessary to transition these changes over several years, after considering the issues discussed above. This would be consistent with many other major changes that have been implemented gradually over the years, including the capital prospective payment system. A phase-in allows hospitals time to adapt to the new reimbursement approach, without creating massive disruption of current arrangements and services. Further, particularly if CMS proceeds stepwise with cost-based weights followed by severity adjustors, a phase-in would reduce the "whip-saw" effect of having hospitals experience negative impacts one year followed by positive impacts the next, or vice-versa.

Transparency of Health Care Information

The proposed rule also discusses the Administration's interest in greater transparency of health care information, including charge and pricing data. According to the rule, the Department of Health and Human Services intends to launch a major health care information transparency initiative in 2006. Several regions will be identified with high health care costs and significant interest in reducing cost and improving quality. The rule solicits comments on several approaches to increase the transparency of pricing and quality information, and how this can be used to stem the growth in health care spending.

Among the possible approaches mentioned are: publishing a list of hospital charges for every region in the country or selected regions; require posting prices or discounts for uninsured patients; or posting total Medicare payments for an entire episode of care (e.g., inpatient, outpatient, and physician payments).

We support the comments submitted by AdvaMed on this issue. We urge CMS to integrate pricing and quality information on appropriate evidence-based protocols. Patients need to know both the costs and benefits of the care they receive, in a format that is understandable and accessible. We also urge CMS to consider appropriate timeframes for measuring quality and costs, and to look across all sites of care delivery to assess efficiency. If an episode of care encompasses a too-short time frame or does not consider the avoidance of inpatient and outpatient encounters, costs and quality may be inaccurately determined.

Attachment 2: J&J's Comments Examples of DRG Adjustments Adopted Through Notice and Comment Rulemaking That Would Be Negated If CMS Implements Severity-Adjusted DRGs in FY 2007				
CURRENT CMS DRG	**Date Originally Adopted by CMS Through Rulemaking**	**Rationale for Change**	**CMS Consolidated Severity- Adjusted (CS) DRG Mapping**	**Impact Of Severity Adjustment***
557 & 558, Drug-Eluting Stent with/without Major Cardiovascular Diagnosis	FY 2003 (original), modified in FY 2006	CMS: "We recognize that the resources surrounding bare metal stents and drug-eluting stents differ appreciably and will continue to keep these cases separate..." Federal Register, Vol. 70, 47294, August 12, 2005	CSA-DRGs 237-242 Percutaneous Caridovascular Procedures **[all coronary angioplasty is grouped here, regardless of whether a stent is inserted]**	DRG 557: -23% DRG 558: -33%
559, Acute Ischemic Stroke with Use of a Thrombolytic Agent	FY 2006	CMS: "We agree...that there is an increased cost in caring for these [stroke tPA] patients including increased use of the intensive care unit, more diagnostic imaging studies, and laboratory and pharmacy resources. We also agree that—(1) the data indicate that patients receiving thrombolytic therapy have increased severity; and (2) reperfusion therapy is a good means to segregate these patients into a separate DRG." Federal Register, Vol. 70, 47288. August 12, 2005.	CSA-DRGs 56-58 CVA & Precerbral Occlusion W Infarction. **(Revert to claissifying tPA back with all other stroke cases, undoing what they did just last year.)**	-35%
551, Permanent Cardiac Pacemaker Implant with Major CV Diagnosis or AICD Lead or Generator	FY 2006	CMS: "Using the MCV list, we tested our assumption that these conditions described a more severe set of cardiovascular surgery patients. We grouped all the cardiovascular surgery patients within MDC 5 based on the presence or absence of an MCV condition. We found that this split was predictive of significantly	CSA-DRGs 228-233 Permanent Cardiac Pacemaker Implant With & W/O AMI, Heart Failure or Shock **(Reverts back to classification based on presence or absence of heart failure, AMI, or shock, rather than Major Cardiovascular**	-17%

		increased resource use for nine surgical cardiovascular DRGs." Federal Register, Vol. 70, 47474, August 12, 2005	**Diagnosis)**	
545, Revision of Hip or Knee Replacement	FY 2006	CMS: "For the FY 2006 IPPS proposed rule, we examined data in the FY 2004 MedPAR file on the current hip replacement procedures (codes 81.51, 81.52, 81.53) as well as the replacements and revisions of knee replacement procedures (codes 81.54 and 81.55) in DRG 209. We found that revisions were significantly more resource intensive than the original hip and knee replacements." Federal Register, Vol. 70, 47305, August 12, 2005.	CSA-DRGs 414-419 Hip Joint Replacement (414-416) & Knee Joint Replacement (417-419) **(Would undo last year's change to recognize the increased resources for revisions.)**	-10%
496, Combined Anterior/Posterior Spinal Fusion	FY 1998	CMS: "In view of the volume of cases involved and the clear differences in resource use, we concluded that it would be appropriate to create additional DRGs to separate spinal fusion cases from the other back and neck procedures... The average charges and lengths of stay for the cases involving both anterior and posterior spinal fusion were markedly greater than for the other spinal fusion cases... [W]e concluded that the magnitude of the differences in both average charges and lengths of stay warranted a further subdivision of the spinal fusion cases." Federal Register, Vol. 62, 45976, August 29, 1997.	CSA-DRGs 413, 421-425, 461-463 (**Combined anterior/posterior spinal fusions appear simply to be regrouped with all other spinal fusions, ignoring the greater resource intensity and LOS associated with these cases and reversing the policy from the FY 1998 final rule.)**	-38%

*Weighted average reduction.

182

June 12, 2006

VIA HAND DELIVERY

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

Novo Nordisk appreciates the opportunity to submit these comments regarding the Inpatient Prospective Payment System (IPPS) Proposed Rule for Fiscal Year (FY) 2007. Novo Nordisk is a focused healthcare company and world leader in diabetes care and other pharmaceutical products. The company has the broadest diabetes product portfolio in the industry and also has a leading position within areas such as hemostasis management. Currently, we are conducting a Phase III clinical trial studying the use of NovoSeven® [Coagulation Factor VIIa (Recombinant)] in Intracerebral Hemorrhage (ICH). We develop, manufacture, and market pharmaceutical products that make a significant difference to our society – patients, the medical profession, and importantly, to Medicare beneficiaries.

Novo Nordisk supports CMS' efforts to improve the accuracy of payment rates under IPPS, and we commend the Agency for examining MedPAC's proposals for reforming the Diagnosis-Related Group (DRG) payment system. In general, we believe that DRG payment reform of the scale proposed by CMS requires significant analysis and consideration in order to ensure adequate payment for hospitals and continued access to care for beneficiaries. In particular, we are concerned that the proposed consolidated severity-adjusted DRG payment system does not account for additional costs related to complexity and resource utilization not associated with patient severity. In order to provide sufficient time to

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evaluate and address this and other issues, and to minimize the administrative and financial burden that may be posed by large-scale DRG payment reform, we do not support implementation of the severity-adjusted DRG system in FY 2007.

Further, Novo Nordisk supports the preservation of the new technology add-on payment mechanism under the current and proposed payment systems in order to provide Medicare beneficiaries access to cutting-edge technology while more accurately reimbursing hospitals for added costs.

I. DRGs: Severity of Illness

DRG Reform must Account for Complexity of Care and Resource Utilization Unrelated to Severity of Illness

Novo Nordisk supports CMS' stated goal of recognizing severity of illness among the Medicare population by implementing a consolidated severity-adjusted DRG system. However, we share CMS' concern, outlined in section II.C. of the preamble, that the proposed severity-adjusted DRG system "does not currently accommodate distinctions based on complexity."[1] As discussed in the proposed rule, the use of some complex technologies is in fact precluded by an advanced degree of disease severity, as illustrated in the example of coronary stents (i.e., the inability to insert a stent may be indicative of a patient's more severe coronary artery disease).

Further, the proposed system will in effect reverse last year's decision to create DRG 559, Acute Ischemic Stroke with Use of a Thrombolytic Agent, which CMS acknowledged was necessary given the "...increased cost...including increased use of the intensive care unit, more diagnostic imaging studies, and laboratory and pharmacy resources,"[2] for stroke patients receiving thrombolytic therapy. Under the proposed severity-adjusted DRGs, ischemic stroke patients receiving reperfusion therapy would be assigned to CSA-DRGs 56-58 with other patients whose stroke care is less complex. This severity-based assignment will also be irrespective of whether the patient is admitted to a non-stroke center, primary stroke center, or comprehensive stroke center, each of which has at its disposal a very different set of resources, technologies and interventions to treat stroke.

Likewise, we are concerned that the proposed severity-adjusted DRGs may fail to recognize that less severely-ill stroke patients may benefit the most from the use

[1] CMS-1488-P, *Federal Register*, Vol. 71, No. 79, Page 24014 (April 25, 2006).
[2] CMS-1500-F, *Federal Register*, Vol. 70, No. 155, Page 47288 (August 12, 2005).

of certain costly technologies, particularly new technologies. Patients who present the best possibility for positive outcomes from thrombolytic reperfusion therapy in ischemic stroke are those seen more acutely after symptom onset and with milder strokes (lower NIH Stroke Scale scores, higher Glasgow Coma scores). The same may hold true for neuroprotectants in ischemic stroke or hemostatic agents in hemorrhagic stroke, therapies which are currently being studied in Phase III clinical trials by separate manufacturers. The proposed severity of illness DRGs could create a disincentive for the use of these and other technologies in the patients most likely to benefit.

For these reasons, Novo Nordisk strongly urges CMS not to implement a severity-adjusted DRG system until a method is developed to account for the facilities-based resources and technologies that may improve outcomes at the expense of increased cost, but do not correlate with a higher degree of illness severity. An extended implementation timeframe will allow CMS to refine the severity-adjusted DRG system to account for additional costs related to complexity and resource utilization that are not associated with patient severity.

II. New Technology

CMS should Preserve the New Technology Add-On Payment Mechanism throughout Current and Future Payment System Reform

In order to ensure that Medicare beneficiaries have continued access to the most effective and highest quality care available, we encourage CMS to continue to provide new technology add-on payments for qualified technologies under the IPPS. Despite the proposed changes to the DRG payment system, hospitals may continue to be under-paid for the use of new technologies because the costs of those technologies may not be reflected in DRG payment rates for two to three years. This would be exacerbated under the proposed DRG changes, where reimbursements for 2007 would be set based on 2002 cost data. As the new technology provision states, add-on payments apply to new medical services or technologies if "based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges...is inadequate."[3] In order to make certain that Medicare beneficiaries receive the highest quality of care available, it is essential that CMS maintain the new technology add-on payment mechanism under IPPS in 2007 and beyond.

[3] SSA §1886(d)(5)(K)(ii)(I).

III. Conclusion

Although Novo Nordisk appreciates CMS' efforts to improve the IPPS, we believe such wide-scale reform as described in the proposed rule should not be implemented in FY 2007. We are particularly concerned that the proposed severity-adjusted DRG payment system will not adequately account for costs related to complexity and resource utilization not associated with patient severity. In addition, we encourage CMS to retain the new technology add-on payment mechanism throughout payment system reform in order to provide Medicare beneficiaries with appropriate access to high-quality care.

Should you have questions or require additional information related to our comments, we may be reached at the numbers listed below. Thank you for your time and consideration of these matters.

Sincerely,

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183

Boston Scientific

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June 12, 2006

HAND DELIVERED/ BY COURIER

Mark McClellan, MD, PhD
Administrator
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Hubert Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates (CMS-1488-P)

Dear Dr. McClellan:

Boston Scientific Corporation appreciates the opportunity to provide comments in response to the Medicare Program's Proposed Changes to the Hospital Inpatient Prospective Payment System (IPPS) and Fiscal Year (FY) 2007 Rates (CMS-1488-P).

As the world's largest company focused on the development, manufacturing, and marketing of less-invasive medicine, Boston Scientific supplies medical devices and technologies used by the following medical specialty areas, all of which provide beneficiary care in the hospital inpatient setting:

- Cardiac Rhythm Management;
- Cardiovascular;
- Endosurgery; and
- Neuromodulation.

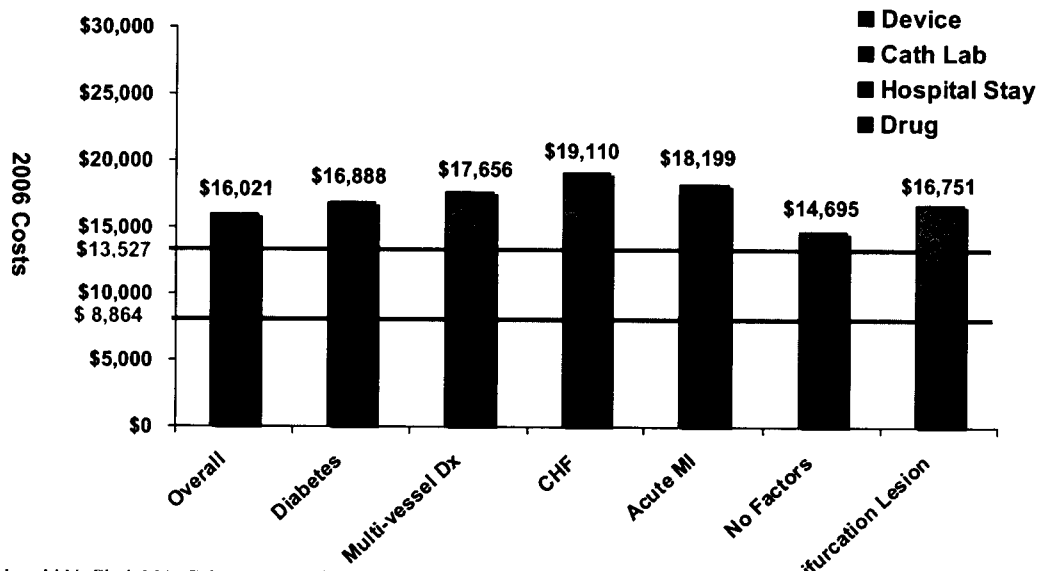
Executive Summary

Boston Scientific fully supports the goal of the Centers for Medicare and Medicaid Services (CMS) to improve payment accuracy in the DRG system and assure beneficiary access to services, including new technology. We recognize and appreciate CMS's significant efforts to meet this objective in the proposed rule. We agree with CMS that appropriately designed changes in the payment method and DRG structure can improve payment accuracy within the IPPS. However we have significant concerns about the methodology proposed by CMS to calculate inpatient hospital payment rates ("cost-based weights"). We are also concerned about mathematical flaws in the calculation of the proposed weights. Moreover, CMS has not demonstrated the value of making substantial changes that are the most significant and complex since implementation of the IPPS. These changes will redistribute billions of dollars and could substantially alter clinical practices. CMS did not present any evidence that the proposed changes would actually improve payment accuracy.

In fact, we believe that the changes would create less accurate payment rates for many services. The example below highlights the cumulative effect of the methodological and mathematical flaws. CMS's

proposed payment rates for FY 2007 would cover only 84% and 55% of costs for drug-eluting stent (DES) patients with and without major Cardiovascular (CV) Diagnoses, respectively.

Figure 1: Estimated Proposed FY 2007 Payments Fall Short of Costs for DES Cases



* Olchanski N, Clark MA, Cohen DJ. Inpatient resource utilization and costs of procedures implanting drug-eluting stents in complex cases: the ARRIVE registry. *Circulation* 2005;111:e310-e359.Costs estimated based on patient-level resource utilization.
[1] $13,527= BSC Estimated Proposed 2007 Medicare payment for DRG 557 (DES w/Major CV Diagnosis)
[2] $8,864 = BSC Estimated Proposed 2007 Medicare payment for DRG 558 (DES w/o Major CV Diagnosis)

Finally, we are concerned about CMS's proposal to implement a severity-adjustment under the IPPS. The payment rate and severity-adjustment changes proposed by CMS are complex and could have far-reaching impact on the delivery of hospital services to Medicare beneficiaries. We believe that the 60-day comment period is not sufficient time for hospitals and other stakeholders to fully assess the proposals. **Therefore, we urge CMS to continue with the current, charge-based payment methodology for FY 2007.**

Below are additional recommendations:

- During FY 2007, CMS should take the following steps to improve the data and methods used to develop cost-based weights: 1) convene an expert panel that develops recommendations to better use information from hospital cost reports and 2) develop an adjustment for charge compression to improve the accuracy of cost estimates for procedures involving implantable medical devices.

- Starting in FY 2008, CMS should adopt cost-based weights using the same methodology and standardization techniques used in the outpatient prospective payment system (OPPS).

- Also starting in FY 2008, CMS should modify the current DRG system to adjust for patient severity and procedure complexity rather than replacing the current system with a modified version of 3M's APR-DRGs as the basis of severity-adjusted DRGs.

- CMS should implement both cost-based weights and severity-adjusted DRGs concurrently in FY 2008. The change to cost-based weights should be phased-in over a three to four-year period.

- Based on inappropriate DRG classification, starting in FY 2007, CMS should reassign:
  - all carotid artery stenting (CAS) cases to DRG 533.
  - cochlear implant procedures to DRG 001.
  - intracranial angioplasty (with and without stenting) cases to DRGs 001 and 002.
- We urge CMS to approve the C-Port System for a new technology add-on payment for FY 2007.
- We support the following proposed changes to the ICD-9 coding system:
  - Addition of procedure code 00.44 (procedure of vessel bifurcation).
  - Mapping of procedure code 37.74 (epicardial leads) into DRGs 515, 535, or 536.

Below we provide additional context, discussion, and policy rationale to support our recommendations.

I. Hospital-Specific Relative Value (HSRV) Weights

Recommendations and CMS Actions Requested

- CMS's proposal contains methodological and mathematical flaws that underestimate the cost of device-intensive cases.
- CMS offers no evidence of longitudinal stability of proposed methodology.
- Charge compression effects are further exacerbated under CMS's HSRVcc methodology. A charge compression adjustment should be implemented after appropriate stakeholder input.
- CMS should develop methods to improve the utility of hospital cost report data for use in FY 2008 rates.
- Hospital-specific relative value method ignores meaningful and valid differences in hospitals' costs.
- CMS should adopt a traditional cost-based weighting methodology, using the same methodology and standardization technique used in OPPS. If CMS decides to proceed with HSRVcc, CMS must fix the flaws, implement a charge compression adjustment, and make other adjustments to improve cost report data used for IPPS.
- CMS should transition traditional cost-based weights over a three to four-year period.

Methodological and Mathematical Flaws
Boston Scientific appreciates CMS's significant efforts in developing cost-based payment weights using HSRVccs. However Boston Scientific has concerns about several methodological and mathematical flaws in CMS's methodology:

- CMS should have used charge-weighted national average cost-to-charge ratios (CCRs) to estimate costs. However, CMS used hospital-weighted geometric mean CCRs, which results in significant distortions in the resulting cost shares for the ten cost centers.
- CMS's approach to calculating CCRs also excludes hospitals with a CCR for routine days below 0.26. As a result, about 238 hospitals, representing 25% of routine charges, are excluded from the CCR calculation. Although these hospitals are excluded from the CCR calculation, they are included in the cost-share calculation.

The cumulative effects of these flaws are distorted relative weights. In particular, relative weights for device-intensive procedures are substantially lower than they would be if the methodological flaws are fixed. For example, an analysis by Chris Hogan from Direct Research, LLC, shows that adjusting for these flaws changes the relative weights from 1.43 to 1.75 for DES (DRG 558); 4.15 to 4.90 for ICD (DRG 515), and 1.77 to 1.97 for Cardiac Pacemaker procedures (DRG 552).

Appendix A contains additional information on these issues.

Longitudinal Analysis

CMS proposes to move to the HSRVcc methodology without offering any evidence that the method actually improves payment accuracy. In addition, CMS offers no evidence on the proposed method's longitudinal stability. Hospitals and other stakeholders have come to rely upon the relative stability of longitudinal payment changes under the IPPS. And yet CMS has not offered any evidence that the new system, which relies upon both claims and cost report data submitted over multiple years, will have sufficient longitudinal stability necessary for hospitals' financial planning.

Charge Compression

The HSRVcc methodology also exacerbates the effects of charge compression. Charge compression refers to hospital charging practices which result in lower mark-ups for higher cost items and services, in particular, implantable devices. Charge compression tends to result in lower relative weights for device-intensive cases, even under the current charge-based payment system. A Lewin study of the current IPPS found that charge compression creates a severe, systematic distortion in payment rates and, in some cases, suppresses DRG relative weights by 20%- 40%.[1] Other studies have also confirmed the existence of charge compression and its negative impact on payment rates for ICD procedures and other advanced technologies.[2,3,4,5]

However, cost-based systems can result in more distorted relative weights without an adjustment for charge compression. For example, when CCRs at the hospital department level for each hospital are used to develop cost estimates, costs will be underestimated for items such as implantable cardiac defibrillators which typically have higher CCRs than the department average CCR. Similarly, when CCRs at the *national* level are used to develop cost estimates, costs for items with higher than average CCRs are understated further, resulting in even lower relative weights for such items.

The impact of charge compression is illustrated in Table 1. In this example, the hospital charges $36,994 for a defibrillator that costs $26,635. However, when CMS's "Supplies and Equipment" cost center's average CCR of 0.34 is applied, the resultant estimated cost is $12,578. Using the cost center's average CCR to estimate defibrillator costs creates an estimated "cost" that is less than half the true cost. This distortion in cost estimates continues through the payment rate-setting process and eventually results in inappropriately low relative weights for defibrillator implant procedures. On the other hand, in the

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[1] Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

[2] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106.

[3] GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf.

[4] The Effect of "Charge Compression" on Reimbursement of Medical Devices under the Medicare Outpatient Prospective Payment System: Preliminary Findings. The Moran Company, April 2003.

[5] Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

generic supply item example, the same method results in an estimated "cost" that is substantially higher than true costs.

Table 1. Impact of Charge Compression

	True Cost	CCR	Charges (Cost / CCR)	Supplies & Equipment Dept CCR	Estimated Cost (Charges * Dept CCR)	Estimated Cost vs. True Cost
Defibrillator	$26,635 [a]	.72 [b]	$36,994	.34 [c]	$12,578	-53%
Supply item	$100	.24 [d]	$417	.34 [c]	$142	+42%

[a] IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2005 through December 31, 2005; Average cost, Hospital Supply Index device mix is 24.4% single chamber, 38.1% dual chamber, and 37.5% CRT-D.
[b] Represents average CCR for ICD system per Lewin Group analysis.[6]
[c] Supplies and Equipment CCR average from proposed FY 2007 IPPS rule.
[d] Estimate from Hogan study on CCRs for supply sub-categories.

One promising recommendation to remove charge compression bias from payment rates is to split up the supplies and equipment departmental CCR into separate CCR adjustments for each supply sub-category. This can be accomplished by leveraging revenue center-specific UB-92 supply charges. By combining data from all hospitals in a regression, CMS could calculate a set of CCR adjustments reflecting national average CCRs for each supply sub-category in the 270-279 revenue center code series. These CCR adjustments would then be applied to improve the accuracy of CMS's estimated costs. While this analytic technique is quite promising, CMS should ensure appropriate stakeholder involvement in the continued process of improving the accuracy of CMS's payment rates before implementing such an adjustment.

Use of cost reports and improving utility of cost report information
Medicare cost reports were not designed for use in prospective payment systems. Currently cost data are not collected at the claim level. Cost reports provide aggregate costs at department or cost center level, and CCRs are derived from the individual hospital cost reports. Costs of items and services at the case and DRG levels are estimated using charge data from claims and cost reports. In 1993 a ProPAC study found routine costs were overestimated by 12.6% and ancillary costs underestimated by 4.9%[7]. The study concluded that "the cost report's reliability is reduced considerably when routine inpatient costs and ancillary costs are analyzed separately" and that cost report data "are clearly not reliable or accurate for analyzing micro-level costs."

Another major concern with using cost report data to derive cost-based weights is the timeliness of cost report data. Under the HSRVcc method proposed by CMS, CMS would use cost report data that are three to four years older than the payment year in question. The age of the cost data raises concerns about the accuracy of CCRs used to estimate costs. Older cost data would not include newer technologies in the calculation of CCRs. When older CCRs are used to estimate costs of procedures in future years, after new technology has been adopted, the methodology will consistently underestimate costs for device-intensive procedures.

Finally, the wide variation in hospital cost reporting practices raises additional concerns about the utility of cost report information for use in prospective payment systems. For example, hospitals have a range of options to allocate overhead expenses. Hospitals also have choices on how to determine Medicare's

[6] Ibid.
[7] J. Ashby, "The Accuracy of Cost Measures Derived from Medicare Cost Report Data," Intramural Report I-93-01 March 1993; ProPAC.

share of costs at the department level. Because CMS has provided great flexibility to hospitals when reporting cost, discerning "costs" at the procedure level is extremely difficult and without appropriate adjustments can result in distorted relative weights under a cost-based payment method.

To study and determine methods of improving hospital cost reports, CMS should assemble an expert panel or work group comprised of hospital finance experts, prospective payment authorities, and hospital charge master personnel. This group could make recommendations on how to better use cost report data when setting PPS weights and should address the following issues:

- Charge compression to ensure that payments for higher-cost implantable devices are not reduced below cost.
- Standardization for hospital accounting and cost allocation practices to minimize the potential for further distortion of the cost estimates. Experts believe that cost report information is biased and overestimates hospitals' routine costs while underestimating ancillary costs.

The panel should report back to CMS by March 31, 2007 so that recommendations may be incorporated and implemented no later than FY 2008.

Use of hospital-specific relative values
Under a hospital-specific relative value method, each hospital's data (whether costs or charges) are converted to relative values. These relative values are then scaled up or down to match the level of costs or charges (depending upon whether the method is used for cost-based or charge-based relative weights) predicted by the hospital's case mix. All other variations in hospital costs or charges are not allowed to affect the calculation of the DRG weights. In contrast, the standardization method used in the current payment method removes hospital-level variation only when Medicare recognizes such variation in another part of IPOP: wage index, indirect teaching expenses, and disproportionate share payments. All other variations are allowed to affect DRG weights.

By ignoring unexplained differences in hospitals' cost differences, the hospital-specific relative value methodology ignores meaningful and valid cost variations. For example, two hospitals in the same city may choose to provide services using different pay structures (one hospital's overall compensation package maybe 10% higher than the other hospital). Under the hospital-specific relative value method, this variation would not be allowed to affect DRG relative weights. To the extent that services using new technology are provided by hospitals that have higher cost structures than other hospitals, the hospital-specific relative value methodology will result in lower DRG relative weights for such services.

Use OPPS methodology for IPPS starting in FY 2008
Boston Scientific urges CMS to use the OPPS methodology, after adjusting for charge compression, to develop cost-based weights for IPPS starting in FY 2008 and phased-in over a three to four-year period. The OPPS methodology offers several advantages over other approaches. First, unlike the MedPAC recommendation in their 2005 report on specialty hospitals, the OPPS approach should be relatively easy to administer for IPPS. CMS's ample experience using the OPPS approach could be leveraged for use in the IPPS. Second, stakeholders also have experience and understand the OPPS approach. Third, using same approach for inpatient and outpatient hospital services would make internally consistent use of both hospital claims and cost reports. Finally, our analysis of several payment approaches leads us to believe that the OPPS method will improve payment accuracy. The HSRVcc method is less accurate while a more accurate system would require greater data collection on the part of hospitals and CMS. In short, we believe that the OPPS methodology, after adjusting for charge compression, offers the right balance between administerability and payment accuracy.

BSC reiterates our recommendation that CMS not proceed with the HSRVcc methodology. If however, CMS decides to proceed, CMS must fix the critical methodology and mathematical flaws discussed above. CMS must also implement a charge-compression adjustment as well as other adjustments to improve the accuracy of cost report data used in the calculation of relative weights. Again, we strongly urge CMS to allow additional time to develop a more sound methodology to calculate cost-based weights rather than rushing to implement a system in FY 2007.

II. DRGs: Severity of Illness

Recommendations and CMS Actions Requested

- CMS should use the existing DRGs (CMS DRGs) as the platform for introducing complexity and severity-related changes.
- CMS should implement a change to the classification system at the same time as changes to the payment rate methodology.

We agree with CMS's fundamental goal of improving payment accuracy through a combination of more accurate payment weights plus improved recognition of patient severity. However we have several concerns about CMS's proposal for consolidated severity adjusted DRGs. First, as noted above, CMS has not demonstrated that the severity-adjustment CMS proposes would improve payment accuracy. In fact, CMS's proposal creates substantial change to payments within and across DRGs, partly because, as CMS acknowledges, the proposed system does not adequately capture procedural complexity.

For example, currently a defibrillator replacement groups to DRG 551 (RW=2.63), the higher paying of the two pacemaker system implant DRGs, while pacemaker replacements currently group to DRG 118 (RW=1.39). However, under CMS's proposal, consolidated severity-adjusted DRGs 243, 244, and 245 would include both pacemaker and defibrillator device replacements. Because severity level is based on patient condition and not complexity of the device, many pacemaker and defibrillator replacements could be paid at a severity of illness (SOI) level 1 (consolidated severity-adjusted DRG 243, RW=1.30), resulting in a 50% decrease in defibrillator replacement payments.

In addition to numerous mismatches and inappropriate payment shifts, basing the severity-based DRG system on APR-DRGs does not reflect changes made to the Medicare DRG system over the past two decades. For example, the separate DRG for DES created in 2003 and further refined in 2005 to adjust for severity and resource use (DRGs 557 & 558) would be eliminated under the proposed consolidated severity-adjusted DRGs. As a result, DES procedures would be placed inappropriately into the same category as bare metal stents.

Only patients with adverse consequences would fall into a higher severity level in many instances. While in certain cases such a policy may be appropriate, our analysis found in other instances, short of the patient becoming septic or having another life-threatening complication, cases would never group into the higher severity level. For example, if a patient receives a CRT-D device with a principal diagnosis of *chronic* heart failure, the procedure would be paid at SOI 2. However, if during the patient stay, the patient suffers an acute episode of heart failure due to poor drug management, the principal diagnosis could be *acute* heart failure which would result in a higher SOI 3 payment for the device implant. We believe that any severity adjustment should allow for an increased severity level even without adverse patient consequences.

A third major concern is that the proposed rule discusses the impact of moving to consolidated severity-adjusted DRGs using FY 2004 inpatient claims rather than the FY 2005 claims used to estimate the

impact of cost-based relative weights and other proposed changes. Using two separate years of claims data to show the impact of major changes made it impossible to assess the overall impact of the changes with any reasonable level of confidence.

Finally, because the new classification system software (the "grouper") was not made available by CMS when the proposed rule was released, we and other stakeholders have not been able to fully study the impact of consolidated severity-adjusted DRGs.

Because of the concerns discussed above, the limited ability to model the impact of consolidated severity-adjusted DRGs, and the limitation of this approach in adjusting for resource use and procedure complexity (i.e., required use of sophisticated medical technology independent of variation in severity of illness), CMS should not implement consolidated severity-adjusted DRGs or any severity-based DRG system in FY 2007.

We urge CMS to implement, concurrent with implementation of cost-based weights, a modified version of the current DRG classification system that adjusts for patient severity and recognizes procedure complexity. CMS could develop severity levels within all of the existing DRGs (or pairs of DRGs, in cases where CC or MCV splits now exist), or identify specific DRGs that may be most appropriate for severity adjustments.

III. Proposed Changes to Specific DRG Classifications

Boston Scientific followed CMS's methods in trimming the FY 2005 MedPAR file, estimating proposed payments, and computing all variables used in the analyses described below.

A. DRGs: Carotid Artery Stents (CAS):

Recommendation and CMS Action Requested

- Assign all CAS cases to DRG 533, Extracranial Procedures with Complications and Comorbidities (CC), to better align clinical homogeneity and resource consumption.

CMS declined to assign all CAS cases to DRG 533 beginning in FY 2006 because data using the relatively new CAS codes were not available in FY 2004 (which was used to set FY 2006 rates). However, we believe that the FY 2005 MedPAR data now has a sufficient number of CAS cases to permit a valid analysis of the cost of CAS cases relative to other procedures in DRGs 533 and 534.

In the FY 2007 Proposed Rule, CMS rejects requests to create a new DRG(s) for carotid stenting or to assign all carotid stenting cases paid under DRGs 534, Extracranial Vascular Procedures w/o CC, to DRG 533. Given that all CAS patients eligible for Medicare coverage must be at high risk for surgery and have one or more comorbid conditions and/or anatomic risk factors, by definition, these patients require a higher level of procedural complexity and resource intensity and should be assigned to DRG 533. However, given that these criteria imposed by CMS's coverage policy cannot always be identified using ICD-9-CM diagnosis codes, these cases may be inappropriately categorized into DRG 534. To address this issue CMS should change the DRG grouper to override existing CC edits so that all CAS cases are appropriately assigned to DRG 533.

Based on our research (described below) we also believe that assignment of CAS cases to DRG 533 would better align resource consumption. We identified CAS claims in DRGs 533 and 534 with diagnosis code **433.10,** *Occlusion and stenosis of precerebral arteries, carotid artery, without mention of cerebral infarction,* containing the following ICD-9-CM procedure codes:

- **00.61,** *Percutaneous angioplasty or atherectomy of precerebral (extracranial) vessel(s);* in combination with **00.63**, *Percutaneous insertion of carotid artery stent(s)*
- **39.50,** *Angioplasty or atherectomy of other non-coronary vessel(s)*; in combination with **39.90** *Insertion of non-drug-eluting stent(s)*

To maximize the likelihood of identifying all CAS cases, we used the older ICD-9-CM procedure codes 39.50 and 39.90 in addition to the new codes 00.61 and 00.63. Similar to the CAS analysis presented in the FY 2007 proposed rule, Boston Scientific's analyses of FY 2005 MedPAR data show CAS charges are higher by $7,532 in DRG 533 and $9,138 in DRG 534 (Table 2).

The data clearly support the assertion that it is more appropriate to assign CAS cases in DRG 534 to DRG 533. Mean CAS charges in DRG 534 ($28,033) are more closely aligned with the overall standardized charges for DRG 533 ($29,263) as well as charges for non-CAS cases in DRG 533 ($28,769). The data also show that assigning CAS claims from DRG 534 to DRG 533 would have minimal impact on standardized charges for DRGs 533 and 534. Average standardized charges would decrease approximately $62 and $563 for DRGs 533 and 534, respectively.

Table 2. Analysis of FY 2005 MedPAR Data: DRGs 533 and 534: Current versus Proposed

DRG	Total Claims	2005 Standardized Charges	
		Mean[1]	SD
Current DRG 533 –All Cases	45,423	$ 29,263	$ 29,731
DRG 533 - CAS cases[2] only	2,796	$ 36,795	$ 25,529
DRG 533 – Non-CAS cases	42,627	$ 28,769	$ 29,920
Current DRG 534 - All Cases	41,700	$ 18,895	$ 11,943
DRG 534 - CAS cases[2] only	2,420	$ 28,033	$ 13,718
Proposed DRG 533 - All cases in DRG 533 and CAS cases[2] from DRG 534	47,843	$ 29,201	$ 29,134
Proposed DRG 534 – All cases except CAS cases	39,280	$ 18,332	$ 11,592

[1]The denominator for the means is all non-missing claims.
[2]CAS cases defined as follows: discharges with 00.61 and 00.63 in combination with 433.10 AND with 39.50 and 39.90 in combination with 433.10.

CMS acknowledges that "the use of carotid stent or stents may increase the complexity and resource use" and the charge data presented by CMS in the FY 2007 proposed rule and internal Boston Scientific analyses show that CAS cases are underpaid in both DRG 533 and 534.

Nonetheless, CMS refuses to assign CAS cases to DRG 533, concluding that "the higher average charges and lower length of stay (LOS) for the cases involving carotid artery stents are likely accounted for by the cost of the device." However, if we exclude charges associated with the stent and embolic protection system, (approximately $4,500), CAS procedure charges in DRG 534 ($23,503) would still be substantially higher than non-CAS charges in DRG 534 ($18,336). This difference of $5,167 is likely attributable to comorbidities and complications among the CAS patients and supports assignment of all CAS cases to DRG 533. Further, our analysis demonstrates that charges for CAS cases in DRG 534 ($28,033) are similar to charges for non-CAS cases in DRG 533 ($28,769).

Despite acknowledging that the device "likely" accounts for the higher costs, the agency speculates that the "hospital's charge markup may also explain the higher charges but lower average LOS," citing a national average CCR for medical equipment and supplies of approximately 34 percent. However, estimating device markups based on the national average CCR for the category of medical equipment and supplies is inappropriate. This broad category encompasses products with very different markup levels. Devices typically have lower mark-ups than the remainder of services in the DRG so the overall charges for carotid stenting are probably deflated relative to everything else in the DRG. In the absence of evidence about markup levels for carotid stents, we urge CMS to rely on its traditional approach of using MedPAR charge data to determine appropriate DRG assignment for carotid stenting.

Additionally, we disagree with CMS's proposal to postpone resolving this issue until the consolidated severity-adjusted DRG system is implemented. CMS already has acknowledged that severity-adjusted DRGs do not adequately capture the costs associated with many medically complex procedures that use advanced medical technology, and that refinements will need to be adopted. CMS has not said how these refinements might work, however, or the time frame for implementing these changes. Thus, relying on future severity adjustments is not a viable alternative for addressing the current inadequacy of payment for carotid stenting procedures.

CMS has recognized the value of carotid artery stenting by expanding coverage to a subset of the Medicare population that is at high risk for surgery. Adequate payment is essential to assure that Medicare beneficiaries have access to the therapy.

B. DRGs: Cochlear Implants

Recommendations and CMS Actions Requested

- Assign cochlear implant procedures (ICD-9-CM codes 20.96, 20.97, and 20.98) to DRG 001, Craniotomy Age >17 with Complications and Comorbidities, and re-label DRG 001, Craniotomy Age >17 with Complications and Comorbidities or Implantation of Major Device.
- If CMS opts to assign procedures that use intracranial neurostimulation devices such as to DRG 543, cochlear implant procedures should also be assigned to DRG 543.

Cochlear implant technology has been available since 1984 and paid by Medicare since 1986. Hospitals that perform cochlear implant procedures have long experienced seriously inadequate reimbursement due to inappropriate DRG classification.[8] This continues to negatively impact patient access to this highly beneficial medical technology which restores hearing to profoundly deafened individuals.

Inpatient hospitalizations for cochlear implant procedures are more clinically comparable to procedures in DRG 001 rather than its currently assigned DRG 049, Major Head and Neck Procedures. Procedures in DRG 049 are performed mostly for diseases such as head and neck cancers, while procedures in DRG 001 include operations on and inside the skull, and implantation of complex devices including intracranial neurostimulators. Cochlear implant procedures require incisions behind the ear to remove a section of temporal bone, followed by microscopic neurotologic surgery, which allow hearing to be restored to the profoundly deaf. The procedure is performed under general anesthesia and is typically completed in 2 to 4 hours.

[8] Kane NM, Manoukian PD. The effect of the Medicare prospective payment system on the adoption of new technology. The case of cochlear implants. *N Engl J Med.* 1989 Nov 16;321(20):1378-83.

We analyzed MedPAR 2005 claims data to assess the resources consumed in cochlear implant procedures compared to other inpatient hospitalizations (Table 3).

Table 3. MedPAR 2005 Cochlear Implant DRG Analysis

DRG	Number of Cases	Mean Standardized Charges	Mean Weighted Costs
All Cochlear Implant Cases (all DRGs)	139	$60,080	$32,629
DRG 049 – All cases	2,356	$33,394	$15,556
DRG 049 – CI cases only	121	$58,078	$31,770
DRG 049 – Non-CI cases	2,235	$32,058	$14,678
DRG 001 – All current cases	23,830	$64,572	$31,514
DRG 001 – Cases with re-assigned CI cases	23,951	$64,539	$31,515

We identified cochlear implant cases using ICD-9-CM diagnosis codes 20.96, 20.97, and 20.98. A total of 139 cases were identified, 87% of which were assigned to DRG 049. Mean standardized charges for cochlear implant cases within DRG 049 were 81% higher than all of the remaining cases within the DRG ($58,078 vs. $32,058). Mean costs that were calculated by using revenue center CCRs (CCR method) applied to revenue center charges followed a similar pattern – cochlear implant cases had costs 116% higher than non-cochlear implant cases ($31,770 vs. $14,678).

The mean standardized charges of DRG 001 were highly similar to those of cochlear implant cases ($64,572 vs. $58,078, respectively). Although the proposed DRG 001 payment ($18,733) still fails to cover the costs of these cases (device cost alone = $25,000, it would be closer to Medicare's 2005 hospital outpatient payment for cochlear implant cases ($25,307). Any cochlear implant case reclassification to DRG 001 would minimally affect average standardized charge or DRG weight.

To implement the change proposed by Boston Scientific, CMS could change the DRG grouper to override existing CC edits for DRG 001 and add an edit so that claims containing ICD-9-CM diagnosis codes 20.96, 20.97, and 20.98 automatically group to DRG 001.

We recommend that CMS assign cochlear implants to DRG 001. However, if CMS opts to move intracranial neurostimulation devices such as Kinetra® from DRG 001 into DRG 543 and revise the DRG title to "Craniotomy with Implantation of Major Device or Acute Complex CNS Principle Diagnosis," we recommend that CMS also assign cochlear implants to DRG 543 given the similar technology complexity, resource use, and clinical coherence.

C. DRGs: Intracranial Angioplasty (With and Without Stenting)

Recommendation and CMS Action Requested

- Assign intracranial angioplasty cases (ICD-9-CM code 00.62) to DRGs 001 and 002, Adult Craniotomy with and without Comorbidities and Complications, respectively.

In FY 2005, when CMS issued the new intracranial angioplasty code (00.62, *percutaneous angioplasty or atherectomy of intracranial vessels)*, it was assigned to DRGs 533 and 534 (Extracranial Procedures *with* and *without* Comorbidities and Complications). We believe the procedures represented by code 00.62

should be assigned to intracranial DRGs 001 and 002 based on clinical coherence and resource utilization within the DRG.

Intracranial angioplasty and stenting is a valuable treatment option for a small group of high risk patients with intracranial atherosclerotic (ICAD) disease. In the United States, approximately 8 to 10 percent of ischemic strokes are caused by intracranial atherosclerosis.[9,10] Most ICAD stroke patients are treated with medical therapy but in some cases, this therapy is ineffective and patients are left at high risk for another stroke. For these patients, intracranial angioplasty and stenting provides a promising minimally invasive alternative in the secondary prevention of stroke with recent publications reporting technical success rates of greater than 90 percent.[11] However, the majority of intracranial stenting procedures currently performed involve the off-label use of balloon expandable coronary stents.

In August 2005, the FDA approved the Wingspan™ Stent System with Gateway™ PTA Balloon Catheter via a Humanitarian Device Exemption. This is the first marketed, FDA-approved intracranial stent in the United States. In contrast to balloon expandable stents, the Wingspan Stent is a self-expanding stent, which addresses some acute access challenges associated with balloon expandable technology.

DRGs 533 and 534 describe and include extracranial procedures. However, ICD-9-CM code 00.62 does not describe an extracranial procedure. Rather, it describes an intracranial procedure. DRGs 001 and 002 encompass almost all intracranial procedures. While most procedures assigned to these two DRGs are open procedures, endovascular intracranial procedures are also assigned to DRGs 001 and 002. For example, code 39.72, describes *endovascular repair of head and neck vessels,* and includes coiling embolization for brain aneurysms, glue embolization, insertion of endovascular grafts and endografts, and repair procedures for arteriovenous malformations.

We understand CMS often assigns new ICD-9-CM codes to the same DRGs as their predecessor codes (in this case, ICD-9-CM code 39.50). However, in accordance with section 533(a) of Public Law 106–554, which requires "more expeditious methods of recognizing new medical services or technology" within the inpatient payment system, CMS has assigned new codes to alternate DRGs when appropriate based on grouping logic, clinical homogeneity, and resource similarity. For example, in August 2001, with creation of additional ICD-9-CM codes for spine refusions, CMS chose to immediately assign these new codes (series, 81.30 through 81.39) to alternate DRG 496 (Combined Anterior/Posterior Spinal Fusion) rather than where the predecessor code (81.09) had been grouped (DRGs 497 and 498, Spinal Fusion with *and* without CCs).[12] CMS took immediate action instead of waiting to analyze historical claims data because the new codes allowed delineation of the fusion technique (anterior versus posterior) and level of spine (e.g., cervical spine), and were therefore, similar clinically to other anterior and posterior techniques in DRG 496.[13]

Intracranial angioplasty code 00.62 is more similar in intensity of clinical training, pre-operative work, peri-procedural time, and treatment risks to other intracranial endovascular procedures than it is to angioplasty, atherectomy and other procedures in the peripheral vasculature. Intracranial angioplasty is performed on patients at much higher risk of death and stroke than peripheral angioplasty/stenting patients.

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[9] Sacco RL et al. Stroke 1995.
[10] Thijs VN and Albers GW, Neurology 2000.
[11] Higashida RT, Meyers PM, Connors JJ et al. Intracranial Angioplasty and Stenting for Cerebral Atherosclerosis : A Position Statement of the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, and the American Society of Neuroradiology. *J Vasc Interv Radiol* 2005; 16: 1281-1285.
[12] Code 81.09 is refusion of spine, any level or technique.
[13] August 1, 2001. *Federal Register.* Vol. 66, No. 148, p. 39842.

Resource intensity is also more analogous to DRGs 001 and 002. Boston Scientific's analysis of 2005 MedPAR 2005 data on intracranial angioplasty and stenting show that charges are more consistent with those observed in DRGs 001 and 002. We considered two separate groups of intracranial angioplasty (with and without stenting) cases in our analyses:

Group (1): Identified intracranial angioplasty cases based on new procedural code, 00.62, with these cases restricted to DRGs 533 and 534.

Group (2): Selected intracranial angioplasty cases based on predecessor procedure code, 39.50, *Angioplasty or atherectomy of other non-coronary vessels*, with these cases restricted to DRGs 533 and 534. We further identified cases associated with intracranial atherosclerotic lesions according to the following primary diagnosis codes:

a) Occlusion and Stenosis of Pre-Cerebral Arteries (433.xx with exclusion for 433.1X)
b) Occlusion of Cerebral Arteries (434.xx)
c) Transient Cerebral Ischemia (437.0, 437.1, and 437.9)

The results of these analyses are reported in Tables 4 and 5, and further support grouping these cases to DRGs 001 and 002. Both the LOS and standardized total charges are dramatically higher for intracranial angioplasty procedures than for overall procedures in DRGs 533 and 534 (3.67 days versus 8.06 days and 1.73 versus 2.20 in DRGs 533 and 534, respectively; $65,403 versus $29,263 and $34,757 versus $18,895 in DRGs 533 and 534, respectively) and were more similar to values observed in DRGs 001 and 002. Further, the mean weighted costs for intracranial angioplasty procedures ($33,047 and $16,617) are more analogous to those costs for overall cases in DRGs 001 and 002 ($31,514 and $17,814, respectively).

Table 4. Group 1 MedPAR Analysis

DRG	Total Discharges	Mean LOS (Days)	Mean 2005 Standardized Charges	Mean Weighted Cost
DRG 001	23,830	9.61	$64,572	$31,514
DRG 002	10,106	4.40	$38,787	$17,814
Cases w/ 00.62 in DRG 533	35	8.06	$65,403	$33,047
Cases w/ 00.62 in DRG 534	< 11	2.20	$34,757	$16,617
DRG 533	45,423	3.67	$29,263	$12,674
DRG 534	41,700	1.73	$18,895	$7,947

We obtained similar results when identifying intracranial angioplasty and stenting cases using the predecessor ICD-9-CM code, 39.50 (Table 5).

Table 5: Group 2 MedPAR Analysis

DRG	Total Discharges	Mean LOS (Days)	Mean 2005 Standardized Charges	Mean Weighted Cost
Cases w/ 39.50 + Primary ICAD Dx in DRG 533	678	8.15	$62,360	$24,468
Cases w/ 39.50 + Primary ICAD Dx in 534	191	2.74	$35,008	$12,742

Intracranial angioplasty cases will continue to be significantly underpaid with the current DRG assignments and proposed FY 2007 payment changes. Boston Scientific believes appropriate DRG assignment for intracranial angioplasty and stenting will improve patient access to life-saving treatment options for intracranial atherosclerotic disease.

The current pending request for reconsideration of a national coverage decision should not deter CMS from reassigning intracranial angioplasty and stenting cases to DRGs 001 and 002. We ask CMS to anticipate the possibility of a positive coverage decision and reassign these cases to a more appropriate DRG to facilitate access to a new and innovative treatment option for patients that do not have other options.

IV. New Technology

Recommendation and CMS Action Requested

- We urge CMS to approve the C-Port® System for a new technology add-on payment for FY 2007.

The C-Port® System received FDA approval in November 2005 and represents an advance in technology that improves treatment options for Medicare patients. The System uniquely creates a mechanical, automated, and interrupted bypass anastomosis. Its use in creating a distal coronary anastomosis does not have clinical precedence and may mitigate some of the negative factors influencing vein graft patency with a hand-sewn anastomosis. It can be used in small coronary arteries, as small as 1 mm in diameter, which can be difficult for surgeons to sew by hand.

Current DRG payments are inadequate for the C-Port® System. The average charge of C-Port deployments per patient is approximately $6,000 as compared to a total procedure charge of approximately $1,800 using U-clips. Neither the charges of C-Port® or U-Clips could have been considered in the recalibration of the CABG DRGs.

We appreciate CMS's consideration of the C-Port® System for a new technology add-on payment, and are pleased that CMS agrees the System meets the cost threshold. However, we believe the C-Port® System meets all three requirements for a new technology add-on payment: improved outcomes, cost threshold, and is a new and unique technology.

CMS provided feedback that the C-Port® System was potentially not considered new, as they felt it was similar to staples currently on the market. However, the System is the first and only new technology for the automated creation of a distal anastomosis of a vein graft to the coronary artery. Additionally, the performance of the automated mechanical anastomosis procedures comprises additional new steps and preparation in the bypass procedure; physicians and OR staff must be trained and proctored to use the equipment, and additional education is required to ensure proper patient selection and outcomes.

CMS also indicated that the C-Port® System does not represent a substantial clinical improvement over current technology. Boston Scientific believes that the C-Port® system improves patient outcomes and procedural reliability by facilitating the creation of a reproducible and compliant, interrupted mechanical anastomosis[14]. Specifically, vein graft patency utilizing the C-Port® Distal Anastomosis Device at discharge and 6 months postoperatively was 99% and 96%, respectively. This compares to hand sewn anastomotic patency rates obtained from historical controls of 88% and 80% at 30 days and six months.

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[14] Matschke KE et al. The Cardica C-Port System: clinical and angiographic evaluation of a new device for automated, compliant distal anastomoses in coronary artery bypass grafting surgery--a multicenter prospective clinical trial. *J Thorac Cardiovasc Surg.* 2005 Dec;130(6):1645-52.

There is no other fully-integrated anastomotic system approved by the FDA for creation of an anastomosis between a blood vessel graft and a target coronary artery.

V. Changes to the ICD-9-CM Coding System

A. Procedure on Vessel Bifurcation

Recommendations and CMS Actions Requested

- Finalize addition of ICD-9-CM procedure code 00.44, *Procedure on vessel bifurcation.*
- Coordinate education to hospitals to clarify proper coding for these procedures by utilizing resources such as Coding Clinic for ICD-9-CM and Medicare Learning Network.

Boston Scientific commends CMS and especially the ICD-9-CM Coordination and Maintenance Committee for the addition of new procedure code 00.44 as listed in Table 6B—New Procedure Codes. We believe that use of this specific code is critically important and directly aligned with many of CMS's reform initiatives to measure quality and outcomes. Data to track angioplasty or stenting interventions at a bifurcation in coronary and peripheral vessels will enable exact, disease-specific measurement for this unique resource-intensive interventional procedure.

B. DRGs: Epicardial Leads

Recommendation and CMS Action Requested

- Finalize mapping of ICD-9-CM procedure code 37.74, *Insertion or replacement of epicardial lead [electrode] into atrium,* to DRGs 515, 535, or 536.

Boston Scientific supports and appreciates CMS's recommendation that ICD-9-CM procedure code 37.74 be assigned to DRGs 515, 535, or 536 when used in combination with ICD-9-CM defibrillator device codes 00.54, 37.96, or 37.98. This change will help assure proper payment when the combination of the device and lead code is reported.

VI. Hospital Quality Data

Boston Scientific supports CMS efforts to improve the quality of care delivered to Medicare beneficiaries. The Deficit Reduction Act requires that CMS expand the "starter set" of 10 quality measures that it has used since 2003, by adopting the baseline set of performance measures as set forth in the 2005 report issued by the Institute of Medicine (IOM) of the National Academy of Sciences, effective for payments beginning with FY 2007.

Boston Scientific believes that quality measures should conform to clinically appropriate processes of care established by peer-reviewed literature or professional consensus. Further, we believe that financial incentives to encourage providers to meet standards based on quality measures of this kind are appropriate. Financial incentives must allow sufficient flexibility to meet the unique needs of individual patients, and not encourage providers to avoid the most difficult cases.

The 21 quality measures selected for implementation appear to conform to clinically appropriate processes of care established by professional consensus, as they were recommended by the IOM and endorsed by the National Quality Forum (NQF). As CMS expands quality measures in the future, it should recognize the special challenges that could occur with measures related to new technology. Process measures regarding the use of particular technologies must provide explicit mechanisms to

recognize new technology promptly and appropriately. If CMS does not recognize use of new devices or technologies, it may hinder patient access to these technologies.

In general, Boston Scientific opposes the adoption of process measures regarding the use of particular technologies or devices because these measures could fail to incorporate new technology into the quality measure and hamper patient access to new, improved technology or devices. Boston Scientific believes that it would be more appropriate to adopt quality measures that assess patient outcomes and allow providers and patients to choose the optimal intervention or course of treatment for patients. Quality measures must be reviewed and updated periodically to reflect new benchmarks and standards of care.

CMS is also charged with reporting on hospital efficiency and costs of care. Boston Scientific believes that reports on cost cannot be separated from reports on quality, and that both cost and quality are components of efficiency. We define efficiency as delivering high quality care at the lowest cost. An efficient provider is not one who provides low cost care, but one who provides high quality care at low costs over a meaningful period of time (i.e., episode of care). Boston Scientific encourages CMS to develop measures that examine quality and costs of care within and across settings and over time, and involve all relevant stakeholders, including medical device manufacturers, in the process.

VII. Value-Based Purchasing

Boston Scientific supports a value-based purchasing program for hospitals that encourages the delivery of high quality care with appropriate payment starting in FY 2009.

A. Measures

A value-based purchasing program is based on measures of efficiency, which consider both quality and cost of care over an appropriate time period, such as an episode of care. Boston Scientific agrees with the IOM criteria that measures of quality of care should focus on effectiveness, safety, patient-centeredness and timeliness. Incentives should be aligned such that physicians and other providers are encouraged to deliver high quality care with patient access to advanced medical technologies. In addition, physicians who participate in clinical trials should not have the data from those trials included in their ratings. This would hinder the development of new procedures and other innovations.

Boston Scientific believes that cost of care measures must conform to clinically appropriate processes of care established by peer-reviewed literature or professional consensus. Examples of costs of care measures that meet these standards are reducing medical errors, reducing rates of surgical complications, reducing preventable hospitalizations, reducing inappropriate use of emergency rooms, eliminating services that have been shown as unnecessary and possibly harmful, and eliminating duplicative procedures through better coordination among providers. Boston Scientific strongly believes that cost of care measures should not be used to compare the "efficiency" of providers who do not deliver the same quality of care.

Boston Scientific supports the open process that CMS has used to develop quality measures, and urges that an open process be used to develop cost of care measures. We encourage CMS to collaborate with consensus-building organizations that allow input from <u>all</u> stakeholders and guarantee transparency when developing, selecting and updating performance measures.

B. Data Infrastructure

CMS must plan for the reporting, collection and validation of performance measures, including both quality and cost of care measures. Boston Scientific urges CMS to develop a strategy for allowing comparisons of quality and costs of care over extended periods of time. This is particularly important with respect to medical devices and technologies that often provide benefits that are realized over an extended timeframe. A one-year timeframe for measuring costs and quality is often too short, and may provide incentives to perform procedures and offer services that are less expensive in the short run and may be inappropriately favored over services that are more expensive in the short run but provide more value over the long-term.

C. Public Reporting

Boston Scientific supports dissemination of accurate information on the value of health care items and services. However, we urge CMS to use caution when releasing such information to ensure that the care being measured is appropriate, that all costs and benefits are included, and that the time frame examined spans the full period over which benefits and costs accrue.

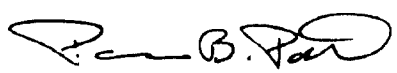
Boston Scientific also believes that any pricing information that is made public must be accompanied by evidence-based quality information for consumers of that information to assess the value of services.

* * * *

Boston Scientific agrees with CMS's goal of improving payment accuracy. However, given the magnitude of the proposed changes and the importance of setting accurate payment rates, CMS should implement broad changes starting in FY 2008.

We appreciate the opportunity to comment on CMS's proposed hospital inpatient rule. If you or your staff has questions, please do not hesitate to contact me (508-652-7492; patelp@bsci.com).

Sincerely,



Parashar B. Patel
Vice President, Reimbursement and Outcomes Planning

cc: Herb Kuhn, Director, Center for Medicare Management
Tom Gustafson, Deputy Director, Center for Medicare Management
Liz Richter, Director, Hospital Ambulatory Payment Group
Marc Hartstein, Deputy Director, Division of Acute Care Service
Scott Reid, Director, Health Policy & Payment, Boston Scientific

Appendix A

Issues in CMS FY 2007 Hospital Inpatient Proposed Rule
Medtronic, Johnson & Johnson, Boston Scientific Meeting with CMS
May 9, 2006

Agenda

- Introductions
- CMS HSRVcc Proposal
- Differences with Traditional Cost-Based Weights
- Assumptions and Apparent Technical Errors
- General Issues with Cost-Based Weights & HSRV
- Consolidated Severity Adjusted DRGs
- Improvement of Cost Data Accuracy
- Next Steps/Recommendations

Improving Payment Accuracy

- MedPAC's recommendations on physician-owned specialty hospitals initiated an important national dialogue on improving the accuracy of DRG payments
- We fully support the goal of improving payment accuracy in the DRG system
- Payments should match costs as closely as possibly
- Inpatient procedures should be neither overpaid nor underpaid
- Impact of proposed changes and methodologies must be fully understood by all stakeholders

CMS HSRVcc Proposal

- Intermingles HSRV and cost-based weights
- Differs significantly with traditional cost-based weights
- HSRVcc: Charge-based HSRV weights reduced to cost weights via application of national CCRs from 10 amalgamated cost centers
- Traditional Cost Weights: Reduce all charges to estimated costs and then calculate weights (similar to MedPAC methodology in specialty hospital report)
- HSRVcc national CCRs exacerbate charge compression

CMS National CCR Calculation

- Cost weights require cost-to-charge ratios for 10 revenue centers.
- MedPAC approach to CCRs
- Match claims to cost reports.
- Calculate cost on each claim
- Summarize to get DRG relative weights.
- CMS "shortcut" approach to CCRs:

- Do not match claims to cost reports.
- Trim and average CCRs from cost reports only.
- CMS uses *hospital-weighted geometric average* CCRs
- Then, 10 national CCRs x 10 US charge totals = 10 cost shares.
- Use cost shares to generate final DRG relative wgt.

Problems with CMS National CCR Calculation

- CMS CCRs are arithmetically incorrect.
- Accept MedPAC method as correct.
- Use algebra to determine how CMS must calculate national average CCR (IF - THEN)
- IF: total US charges x CCR = total US cost,
- THEN: CCR = charge-weighted average of hospital CCRs (not hospital-weighted, not geometric mean).
- Empirically important mistake - next slides.

Simple Example Showing Correct and Incorrect Arithmetic

	Cost	=	CCR	*	Charges
Step 1: Three hospitals, $1 cost each, $3 total costs					
Hospital 1	$ 1.00	=	0.10	*	$ 10.00
Hospital 2	$ 1.00	=	1.00	*	$ 1.00
Hospital 3	$ 1.00	=	1.90	*	$ 0.53
Correct US total	**$ 3.00**		??		**$ 11.53**
Step 2: Calculate US Average CCR three ways					
Unwgtd mean			1.00		
Unwgtd geo mean			0.79		
Charge wgtd mean			0.26		
Step 3: Calculate US total cost from US charges * US CCR					
Total w/ unwgtd mean	$ 11.53	=	1.00	*	$ 11.53
Total w/ unwgtd geo mean	$ 9.06	=	0.79	*	$ 11.53
Total w/ charge wgtd mean	**$ 3.00**	=	**0.26**	*	**$ 11.53**

National Average CCRs, CMS Versus Charge-Weighted

Charge Grouping	**CMS, published**	Calculated, CMS methods	**Calculated, Charge-Weighted**
Routine Days	**0.85**	0.87	**0.55**
Intensive Days	**0.72**	0.73	**0.48**
Supplies & Equipment	**0.34**	0.34	**0.33**
Therapuetic Services	**0.35**	0.36	**0.29**
Laboratory	**0.25**	0.26	**0.20**
Radiology	**0.24**	0.25	**0.21**
Other Services	**0.51**	0.52	**0.46**
Drugs	**0.26**	0.26	**0.22**
Operating Room	**0.37**	0.38	**0.32**
Cardiology	**0.20**	0.20	**0.21**

CMS CCRs Yield Grossly Incorrect Total Costs

	With CMS CCRs	With Charge-Weighted CCRs
Total charges on File ($B)	$ 315	$ 315
Estimated raw cost (charges x CCRs, ten categories, $B)	$ 134	$ 107
Estimated 2005 cost (raw cost x 0.92 to account for 2003 CCR vs 2005 chgs, $B)	$ 123	$ 98
Actual 2005 payment on file, $B.	$ 100	$ 100
Estimated 2005 payment-to-cost ratio	**0.812**	**1.022**

Hospitals Trimmed out of Routine CCR Calculation Have High Charge Per Day

	With CMS CCRs	With Charge-Weighted CCRs
Total charges on File ($B)	$ 315	$ 315
Estimated raw cost (charges x CCRs, ten categories, $B)	$ 134	$ 107
Estimated 2005 cost (raw cost x 0.92 to account for 2003 CCR vs 2005 chgs, $B)	$ 123	$ 98
Actual 2005 payment on file, $B.	$ 100	$ 100
Estimated 2005 payment-to-cost ratio	**0.812**	**1.022**

Large Impact on DRG Weights
(MDC-Medsurg categories with largest gains and losses)

MDC	MDC title	Med or Surg	2005 PPS discharges	Payment change, CMS methods	Payment change with charge-weighted CCRs
19	Mental Diseases,Disorders	**MED**	112,111	64%	46%
05	Circulatory System	**SURG**	1,068,862	-16%	-9%

CMS CCR Values - Conclusion

- Several factors suggest CMS CCRs are wrong.
- They are algebraically incorrect. Total US charges x charge-weighted CCR = total US cost.
- CMS CCRs differ substantially from charge-weighted CCRs.
- CMS CCRs imply large negative Medicare 2005 inpatient margin. Charge-weighted CCRS imply 2% positive margin.
- CMS approach trims out hospitals with genuinely high routine charge per day, accounting for over one-quarter of routine charges. Those hospitals are excluded from CCR calculation but included in cost-share calculation.
- CMS CCRs substantially exaggerate the impact of moving to cost-based weights.
- Large negative impact on cardiovascular surgical procedures.

PPS Payment Trends:
Last 5 and 10 Years

	Cumulative Change from 1996	**Cumulative Change from 2001**
Market Basket	36.5%	18.4%
PPS Update	25.6%	17.2%
Average Payment Per Case - All	32.7%	24.1%
Average Payment Per Case - Urban	27.9%	19.1%
Average Payment Per Case - Rural	53.7%	44.9%
Average Payment Per Case - Major Teaching	19.1%	14.0%

Impact of New DRG Weights

- Very significant redistribution
- Trend is from large, urban and teaching to small, rural and non-teaching
- And from complex or high tech to longer-stay cases
- Favors room and board cost centers over ancillaries
- Cardiology is hit particularly hard
- For many classes of hospitals, the proposed regulation is like a "MB minus" update

All Hospitals (3,522)	+.1%
Large Urban (1,391)	+.1%
Other Urban (1,126)	-.8%
Urban, at least 300 beds (580)	-1.1% to -1.5%
Rural (1,005)	+3.0%
Major Teaching (237)	-.9%

Issues Raised by HSRVcc

- Hospital-specific relativity may be questionable policy
- Unnecessary change since current standardization policy adjusts for differences due to wage levels, teaching and disproportionate share
- HSRV reduces the range of variation between low and high DRG weights
    - Long-time concern of PPS experts that this could deter access to complex care
- HSRV particularly disadvantages surgical cardiac care
- Yet research found that losing hospitals surprisingly have lower charges for expensive cardiac care than winning hospitals
    - They lose because their overall charge levels are higher, but cardiac mark-up is less
    - A possible conclusion???: these hospitals should increase cardiology charges!

Issues Raised by Cost-Based Weights

Is payment accuracy increased?

- Accuracy and completeness of cost report
- 1993 ProPAC study found routine costs were overestimated by 12.6% and ancillary underestimated by 4.9%
    - Study concluded that …
        - "The cost report's reliability is reduced considerably when routine inpatient costs and ancillary costs are analyzed separately."
        - Cost report data *"are clearly not reliable or accurate for analyzing micro-level costs"*
- 1988 ProPAC recommendation to use cost-based weights cited concern with cost report data
    - "cost report data may, in some cases, produce imprecise DRG weights"
    - "Secretary should verify the accuracy of cost report data and implement changes as necessary"

Issues Raised by Cost-Based Weights
Is payment accuracy increased?

- Only about 15% of cost reports are audited
- Charge compression leads to under-estimation of the cost of higher cost items and services
- CCRs assume that all items within a department get the same markup, but expensive items typically have a lower percentage markup than inexpensive ones
- Circularity of using estimated costs to calculate the weights and then measuring their accuracy by comparison to the same estimated costs

How Can You Tell That Accuracy Has Improved?

- Typical MedPAC evaluation is tautological.
- MedPAC evaluations show weights based on "cost" yield payment closer to "cost"
- Does not provide an independent assessment of the accuracy of "cost"
- Is there any independent benchmark for accuracy of cost estimate?
- What about psychiatric PPS (IPF PPS) per-diem rates?
- Psych discharges split 33%/66% IPPS facilities/psych facilities
- Psych facilities paid under new per-diem IPF PPS (not IPPS)
- Stand-alone psychiatric facilities give a clean measure of cost and profitability of this line of services
- Psych should be "acid test" for accuracy: proposed IPPS '07 methods result in 41% payment increase.
- So, how does psych payment compare, IPPS vs IPF PPS?

Approximate Payment per Day for Psychiatric Cases, IPPS vs. Psych PPS

	Discharges Now Paid Under IPF-PPS (psych PPS)	IPPS (general PPS)	% Diff.
Number of Discharges, 2005, (MedPAR)	586,000	233,000	
Raw 2005 Payment per Day (MedPAR)	$ 635	$ 752	18%
Net out IPF-PPS short stay adjustment		0.908	
Net out IPF-PPS casemix adjustment		0.979	
Adjusted 2005 Payment per Day	$ 635	$ 668	5%
Increase Under 2007 Proposed Weights		41%	
Proposed Payment Per Day, 2007 Wgts.	$ 635	$ 943	48%
Memo: Check with theoretical IPF-PPS rate			
Memo: IPF-PPS 2005 base rate	$ 576		
Memo: IPF-PPS avg ECT pmt per dischg	$ 25		
Memo: Theoretical IPPS avg pmt per day excl.	$ 601		

What Changes Might Improve Cost Report Data and the Accuracy of Cost-Based Weights?

- Establish cost report rules and guidelines to bring more consistency and uniformity across hospitals
- Create separate cost center for high-cost implantable devices
- Use multiple per diem rates for room & board
- Adjust for charge compression
- Exclude pediatric cases in calculating CCRs
- Increase the number of cost report audits and the number of items audited

What concerns are raised by the substantial redistributions?

- Could patients needing care in complex DRGs experience access problems?
- How will the changes affect the financial viability of certain hospitals?
- How might hard-hit hospitals respond?
- Reduce charity care?
- Cut unprofitable services like burn and trauma care?
- Change their service mix?
- Close?

- Could the changes discourage use of technology-intensive procedures that lead to lower lengths of stay?

APR DRGs

- CMS proposes to implement a consolidated version of APR DRGs in FY 2008 or earlier
- Assignment is based on severity not complexity
- Device use adds complexity but not severity
- Therefore, device use may not affect DRG assignment
- How will severity-adjusted DRGs affect new technology thresholds and the ability for a new technology to qualify for an add-on payment?
- Could DRG specificity be improved in other ways?
- Redesign selected DRGs to better reflect patient severity based on CMS analysis and outside input
- Revise and refine the complication/co-morbidity list
- Should ICD-10 be implemented before moving to APR-DRGs?
- Greater incentive for up-coding: proposed rule indicates CMS likely will apply a prospective adjustment to the rates

Next Steps/Recommendations

- MedPAC examine technical issues in CMS methodology
- CMS withdrawal of HSRVcc weights this year
- Issuance of charge-based weights for FY 2007
- Recommendations to improve collection of actual cost data under PPS
- Cost-report based DRG reforms follow cost data reforms

Appendix

Consolidated Severity DRGs

- Impact of CS-DRG combines:
- Severity adjustment (intended)
- DRG vs. APR-DRG mismatch (unintended?)
- DRG/APR-DRG mismatches
- Some are easy to spot (e.g., no biliateral hip APR-DRG).
- Some are more subtle (APR-DRG and DRG classify cases into different DRGs).
- Mismatches not resolved on CMS file released with 2007 proposed rule.
- CS-DRG should be thoughtfully restructured to avoid unintended impacts of APR-DRG/DRG mismatch.

A Few Examples of CS-DRG and DRG Mismatch

Using 2004 MedPAR with CS-DRG as released with 2007 proposed rule:

- DRG 103, heart transplant: CS-DRG weight is one-third lower, does not classify some cases as

transplant.

- DRG 471, bilateral leg joint: CS-DRG weight 19% lower; no separate bilateral joint APR-DRG.
- DRG 123, cardiac death: CS-DRG weight is one-quarter lower; splits cases across DRGs, only half at severity level 4
- DRG 496 chemotherapy with acute leukemia: CS-DRG weight 36% lower does not recognize this high-cost subset of cases.

184

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

Henry Alder
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June 9, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, CMS-1488-P

Dear Dr. McClellan:

On behalf of Ethicon Endo-Surgery, Inc., a Johnson & Johnson company, we wish to submit our comments to the Center for Medicare and Medicaid Services (CMS) proposed rule on the Medicare Hospital Inpatient Prospective Payment System (PPS) and Fiscal Year 2007 Rates published on April 25, 2005 in the Federal Register. Ethicon Endo-Surgery, Inc. manufactures and distributes minimally invasive surgery products used for open and laparoscopic procedures and natural orifice procedures.

Johnson & Johnson has already submitted extensive comments discussing CMS' proposed changes with respect to the (1) methodology used to calculate the diagnosis-related group (DRG) relative weights, (2) charge compression and (3) changes to the DRG classification system to better account for patient severity (Johnson & Johnson letter from Kathy Buto to CMS dated June 9, 2006). Therefore, Ethicon Endo-Surgery's comments will principally focus on the impact of CMS' proposed changes on patient access to advanced technologies, specifically for the treatment of morbid obesity.

In that regard, our greatest concern with the proposed rule is the threat that it poses for Medicare beneficiary access to the latest medical advances including obesity surgery. On February 21, 2006 Medicare issued a National Coverage Decision for bariatric surgery, providing coverage (access) to beneficiaries for open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) in hospitals certified as Centers of Excellence by the American College of Surgeons and the American Society for Bariatric Surgery.

In particular, we have great concerns about the proposal to change the calculation of the diagnosis related group weights for DRG 288 – O.R. Procedures for Obesity. DRG 288 will see a –12.4% payment change in FY 2007. The proposed FY 2007 base payment is expected to be $9201.59. For FY 2006, the base payment is $10,502.08.

The current FY2006 Medicare payment for DRG 288 ($10,502.08) does not cover last year's average cost for obesity surgery that is calculated to be $12,017 (FY 2005 MedPAR data). That means bariatric surgery Centers of Excellence will incur a greater financial loss in FY 2007 of $2815.41 ($12,017 - $9201.59) when providing open or laparoscopic gastric bypass to morbidly obese Medicare patients who

are severely ill with comorbidities including Type 2 diabetes, hypertension, sleep apnea and various orthopedic problems. Even if CMS fixes the flaws in the current methodology as described in the J&J comment letter, the impact would still be onerous to Bariatric Surgery Centers of Excellence, changing the impact from – 12.4% to – 7 %. Reductions of this magnitude will certainly restrict access of Medicare beneficiaries to obesity surgery in Bariatric Surgery Centers of Excellence.

In FY 2008 Bariatric Surgery Centers of Excellence will see additional changes in hospital payment for severity-adjusted obesity surgery DRGs. These changes could have a significant impact on individual Centers of Excellence, making it more difficult to deliver innovative minimally invasive procedures such as bariatric surgery.

We recommend delaying the implementation of the IPPS for a year until CMS can make significant changes in the rate-setting system next year to account for patient severity. We understand the American Hospital Association is supporting a one-year delay for similar reasons. In our opinion, the 2007 proposal, if implemented, would unnecessarily disrupt current positive trends that reflect medical advances such as obesity surgery that enable less invasive patient care.

Again, we thank CMS for the opportunity to comment on the proposed changes to the hospital inpatient prospective payment system and FY 2007 rates. Please feel free to contact Henry Alder at 513-337-3201 if you require additional information.

Sincerely,

Henry Alder

cc. Kathy Buto – J&J
Marc Hartstein – CMS

patient_group	patient_group_description	cases	average_los	average_medicare_reimb	average_charges	average_cost
1	DRG 288	11335	3.7	13727	37755	12017
2	Diag 278.01	210288	6.1	9393	26172	9226
3	Proc 44.31	734	4.6	14698	37037	12828
4	Diag 278.01 and Proc 44.31	724	4.5	14480	36513	12684

Attachment 184

America's Health
Insurance Plans

185

Karen Ignagni
President &
Chief Executive Officer

June 12, 2006

Mark B. McClellan, M.D.
Administrator
Centers for Medicaid & Medicaid Services
Department of Health and Human Services
Attention: CMS–1488–P
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

BY HAND DELIVERY

RE: CMS–1488–P

Dear Dr. McClellan:

I am writing on behalf of America's Health Insurance Plans (AHIP) in response to the notice of proposed rulemaking, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates," published in the Federal Register (71 FR 23996) by the Centers for Medicare & Medicaid Services (CMS) on April 25, 2006. AHIP is the national trade association representing nearly 1,300 member companies providing health insurance coverage to more than 200 million Americans. The proposed changes to the DRG system are of significant interest to AHIP's member organizations, many of which utilize the payment methodology under the Medicare inpatient hospital prospective payment system (IPPS) to establish rates paid to hospitals for inpatient services for individuals with private insurance and for beneficiaries enrolled in Medicare Advantage plans.

AHIP supports efforts to refine the DRG-based payment system under IPPS to better account for severity of illness among patients. We believe that this goal is best served by ensuring transparency in the payment methodology; adopting changes in a manner that is least disruptive for entities using the DRGs to make payments and vendors that facilitate their use of the methodology, as well as hospitals receiving payments calculated under this payment mechanism. Our detailed comments appear below.

General Comments

CMS has provided a 60-day comment period on the proposed rule and notes that there would be a statutorily required 60-day period between issuance of the final rule and the October 1, 2006

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effective date of the changes. AHIP has serious concerns about the adequacy of these time frames. As discussed below, we believe that additional information regarding the proposed changes to the DRG methodology is needed to permit interested parties to evaluate them and provide well-informed comments. APR-DRGs would be a significant conceptual shift requiring replacement, rather than simply refinement, of the longstanding CMS DRG system. It is unlikely that health plans, hospitals and other affected parties would be able to prepare to implement the new system in the 60-day period proposed. Accordingly, we strongly recommend that, in order to provide time for additional public comment based upon more detailed information about the proposed methodology and to provide sufficient time for implementation of the DRG system revisions that are ultimately adopted, that CMS implement the changes no sooner than FY 2008.

Specific Comments

DRG Reclassifications

In the Preamble to the proposed rule, CMS states:

> Given the changes we are proposing, we believe that hospitals would be interested in understanding how a given case would be assigned to a consolidated severity-adjusted DRG under the new system. In order to facilitate understanding of the underlying severity DRG concepts and logic, we are providing a link below to 3M's Web site for the duration of the comment period where users can access information related to the proposed consolidated severity-adjusted DRGs... (71 FR 24027)

The DRG patient classification and severity level grouping system should be transparent. As noted above, we strongly believe that it is critical for health plans and other affected parties to have access to sufficient information to understand fully the operation and impact on payments of the proposed changes to the DRG system. This information is important for two reasons:

- **Opportunity to provide meaningful comments.** To perform a thorough evaluation of the proposed use of the APR DRG system developed by 3M, it is essential that interested parties have detailed information that permits them to analyze the operation of the payment mechanism (e.g., whether certain cases would be included in the same DRG after refinement) and compare it to the current methodology and other options for refinements. We are concerned that the information provided through the link to the 3M Web site along with the availability for purchase of the Expanded Modified MedPAR data used by CMS in its simulations are not sufficient to permit the analysis to support well-informed comments.

  AHIP recommends that CMS provide additional details regarding the methodology for classifying patients into DRGs under the proposed modifications and the operation of the GROUPER used to assign severity levels, as well as providing access to the programs for assigning historical data to the

severity-adjusted DRGs. We also recommend that CMS provide a further opportunity for review and comment following release of this information.

- **Implementation of DRG classification system changes.** The 3M APR-DRG system under consideration by CMS is a proprietary system unlike the DRG system. If this system is adopted, it will be essential for CMS to provide full disclosure and transparency to vendors, health plans and others of all aspects of the ARR-DRG system so that these parties can fully replicate all elements of the payment mechanism. We recommend that CMS explicitly indicate that details of the revised DRG system will be fully disclosed to the same extent as details of the present system.

DRGs: Severity of Illness

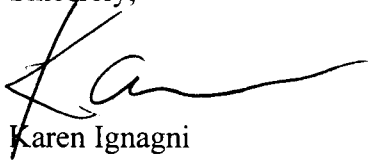
- **Consider alternative methods for refining DRGs.** The Preamble to the proposed rule states:

> Although we discuss the consolidated severity-adjusted DRGs in this proposed rule, we are interested in public comments on whether there are alternative DRG systems that could result in better recognition of severity than the consolidated severity-adjusted DRGs we are proposing.... However, it is possible that the public comment process will present compelling evidence that there are potential alternatives to the consolidated severity-adjusted DRG system for us to consider that could more effectively recognize severity of illness. (71 FR 2401)

As discussed above, it is our understanding that additional information is necessary for interested parties to comment knowledgeably on the proposed APR DRG methodology. This more detailed analysis could lead to the development of "compelling evidence" that would merit CMS consideration of one or more alternative methodologies as suggested in the Preamble language quoted above. Therefore, we believe that it will be important for CMS also to provide a further opportunity to identify viable alternatives and recommend that CMS provide for an additional opportunity to comment not only on APR DRGs but other viable methodologies.

AHIP appreciates the opportunity to comment on the proposed rule. If you would like to discuss any of the issues we have raised or would like additional information, please contact me at (202) 778-3203 or at kignagni@ahip.org or Candace Schaller, Senior Vice President, Regulatory Affairs at (202) 778-3209 or cschaller@ahip.org.

Sincerely,



Karen Ignagni

186

ST. FRANCIS MEDICAL TECHNOLOGIES, INC

June 8, 2006

BY HAND DELIVERY

Mark B. McClellan, Administrator
Centers for Medicare and Medicaid Services
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Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

JUN - 9 2006

Re: CMS-1488-P (Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates)

Dear Administrator McClellan:

St. Francis Medical Technologies, Inc. ("SFMT") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services ("CMS") proposed rule related to the fiscal year 2007 inpatient hospital prospective payment system (" Proposed Rule").[1] SFMT is engaged in the discovery, development and marketing of novel treatments for degenerative spinal disorders worldwide, focusing on minimally invasive technologies to treat degenerative spine problems that help patients quickly regain their mobility. For one of our technologies, the X STOP® Interspinous Process Decompression (IPD®) System ("X STOP "), we applied for an add-on payment under the inpatient prospective payment system ("IPPS") effective October 1, 2006. We were pleased to see that CMS agreed that the X STOP meets two of the three add-on criteria and we noted the agency's concerns about satisfying the substantial clinical improvement criterion. For the reasons discussed below and in the attached document ("Appendix A"), SFMT believes that the X STOP satisfies this criterion and thus CMS should grant our application for add-on payments effective October 1, 2006.[2]

BACKGROUND

As described in more detail in Appendix A, X STOP is a new minimally invasive, stand-alone alternative treatment for lumbar spinal stenosis ("LSS"), that received premarket approval by the Food and Drug Administration ("FDA") on November 21, 2005. The X STOP is placed between the spinous processes to limit extension of the symptomatic level(s), yet allows flexion, axial rotation and lateral bending. This provides a potential alternative to conservative and surgical treatments.

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1 71 Fed. Reg. 23996 (Apr. 25, 2006).

2 All of the comments on the Proposed Rule contained herein relate to "New Technology" issues.

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Consistent with CMS timeframes for IPPS add-on applications, SFMT submitted the required information to CMS in 2005 and participated in the Town Hall Meeting on the add-on applications in February of this year. In the Proposed Rule, CMS stated its belief "that the device satisfies the newness and cost threshold criteria for new technology add-on payments." 71 Fed. Reg. at 24073. At the same time, the agency said that it had some issues with respect to the substantial clinical improvement criterion, most of which were the result of concerns identified at an August 2004 meeting of the Center for Devices and Radiological Health ("CDRH") advisory panel. These concerns involve: (i) proper patient selection; (ii) the lack of objective endpoints (especially radiographic endpoints); (iii) overall low clinical efficacy rate in the study population; and (iv) the FDA approval "on the condition that it be used in the context of a long term (5 year) follow up study." Id. In addition, CMS noted that there seemed to be contradictory information from SFMT and a presenter at the Town Hall meeting regarding the setting in which the device is used. Id. at 24073-74.

DISCUSSION

SFMT agrees with CMS that, based on information previously provided to CMS, we have demonstrated that the X STOP meets the newness and cost threshold criteria for a new technology add-on and thus we focus on the substantial clinical improvement criterion. Under the Medicare regulations, a service or technology meets this criterion if it "represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." 42 C.F.R. § 412.87(b)(1). For reasons detailed below and in Appendix A, under this standard, there is no question that the X STOP represents an advance that substantially improves the treatment for Medicare beneficiaries with LSS. Indeed, the X STOP fills a therapeutic gap between conservative treatment and highly invasive surgical procedures. Moreover, as we discuss below and in Appendix A, the concerns identified by CMS do not disturb our demonstration that the X STOP represents a substantial clinical improvement.

I. The X STOP Represents a Substantial Clinical Improvement for Beneficiaries with LSS

The regulatory standard for satisfying the substantial clinical improvement criterion centers on whether the technology substantially improves the diagnosis or treatment of Medicare beneficiaries. Moreover, in the context of approving another spinal treatment for new technology add-on payments (InFuse™), CMS said that "[o]ne of the criteria for substantial clinical improvement classification is avoidance of surgery." 68 Fed. Reg. 45346, 45391 (Aug. 1, 2003). As a result, we address how the X STOP fits within the treatments available to Medicare beneficiaries with LSS.

As discussed in more detail on page 5-6 of Appendix A, the therapeutic options for patients with LSS fall in two distinct categories. The first category is nonsurgical management of the ailment (also known as conservative therapy) and includes medications, exercises, physical therapy, and limits on physical activity. The second category involves surgical options, with the procedures (e.g., lumbar spinal decompression, laminectomy, fusion) being invasive and

often associated with significant rates of complication. These categories leave a significant gap in the continuum of care from conservative therapy to invasive surgery.

It is this treatment gap that X STOP, and only X STOP, currently fills. It is the only minimally invasive implant that is currently on the market in the United States. With no other technologies currently available in this treatment gap, X STOP should be viewed as a substantial clinical improvement. Considering the issue more broadly and comparing X STOP to conservative therapy yields the same conclusion – i.e., X STOP substantially improves the treatment of beneficiaries with LSS who utilize this conventional therapy. This is evident from the review of the X STOP clinical literature that is contained in pages 11 - 15 of Appendix A. Included in this discussion are study results showing success rates in the 54% to 73% range for the X STOP group compared to success rates in the control (conservative therapy) group in the 6% to 24% range (Appendix A at page 12 (Table 2)).

For reasons explained in Appendix A, it is difficult to design a randomized clinical trial comparing X STOP to the more invasive surgical treatments. However, an analysis comparing the results for the X STOP procedure and a laminectomy procedure has been done. This analysis found comparable success rates between the two procedures. SFMT submits that since the X STOP can be performed under local anesthesia, is associated with fewer and less severe complications, and has a quicker recovery, the X STOP also represents a substantial clinical improvement compared to this other end of the treatment spectrum for beneficiaries with LSS.

Considering the issue of avoidance of surgery, SFMT believes that the X STOP should be considered a substantial improvement just as the agency considered InFuse™ a substantial clinical improvement. That service involved a surgical procedure that, if successful, avoided a bone harvesting procedure. 68 Fed. Reg. at 45391. Similarly, if the minimally invasive X STOP procedure involving soft tissue and bony removal, and risk of neural injury is successful, it can avoid a more invasive procedure such as a laminectomy and thus also should be considered to be a substantial clinical improvement.

II. The Agency's Concerns About Substantial Clinical Improvement Do Not Withstand Scrutiny

As noted earlier, CMS identified a number of concerns about the X STOP meeting the substantial clinical improvement criterion. A number of these concerns were voiced at an FDA advisory panel meeting in August 2004, more than a year before the FDA approved the X STOP. As explained in Appendix A at pages 8-9, SFMT clearly satisfied these concerns given that the X STOP was granted premarket approval by the FDA in November 2005. Nonetheless, we demonstrate below why none of these concerns disturb the above showing that the X STOP represents a substantial clinical improvement for beneficiaries with LSS.

A. Proper Patient Selection

The August 2004 FDA panel cited a need to identify the patient population most likely to benefit from the X STOP. Subsequent to the panel meeting, SFMT provided additional analyses

to the FDA that identified patients with moderately impaired physical function at baseline as those most likely to benefit from the X STOP. This must have allayed the concerns of the FDA since this is the patient population identified in the "Indications for Use" in the product labeling for X STOP. Since the FDA's concerns about proper patient selection were allayed, CMS likewise should not have concerns about patient selection.[3]

B. Objective Endpoints

At the August 2004 panel meeting, some concerns were voiced regarding the lack of objective endpoints (including radiographic endpoints) demonstrating the mechanism of effect. Subsequent to the panel meeting, SFMT supplemented the showing of the mechanism of effect on the spine in cadavers with *in vivo* clinical radiographic data (magnetic resonance imaging) supporting that showing. Based on the new information that SFMT provided that included radiographic endpoints, the concern raised at the August 2004 panel meeting was ameliorated. In fact, there was a subsequent panel meeting in September of 2005 during which time the panel again looked at mechanism of action endpoints, but downplayed their importance in favor of patient-oriented outcomes. Thus, the concern about objective endoints should not detain CMS in its review of our add-on request.

C. Clinical Efficacy Rate

CMS noted that the FDA advisory panel mentioned a low clinical efficacy rate in the study population. Here again, subsequent to the August 2004 panel meeting, SFMT worked with the FDA to address this concern and did so successfully. The issue of clinical efficacy is discussed extensively in Appendix A, which we believe also demonstrates why CMS should not have concerns about the clinical efficacy of the X STOP and should grant our request for add-on payments. While Appendix A addresses the issue in detail, we note the following highlights of that discussion:

- The measurement tool utilized in the X STOP studies (the ZCQ – Zurich Claudication Questionnaire) is the most precise, validated measurement tool for the LSS population;
- Using this and other tools, the X STOP Pivotal Trial demonstrated that the X STOP is clinically superior to conservative treatment, which is the only valid comparison population (as noted by a separate FDA advisory panel that met in September of 2005).
- As explained in Appendix A (pages 17-19), in the X STOP Pivotal Trial, the definition of clinical success was defined too stringently (requiring validated threshold criteria be met

[3] We are aware that CMS does not "employ FDA guidelines to determine what drugs, devices or technologies qualify for new technology add-on payments under Medicare" because the substantial clinical improvement criterion is different than the FDA standard of safety and efficacy. 69 Fed. Reg. 48916, 49011 (Aug. 11, 2004). Here, however, CMS is citing concerns raised in the FDA approval process for X STOP. Thus, concerns resolved to the FDA's satisfaction should suffice for these purposes as well. Furthermore, in prior discussions, CMS staff has raised questions as to whether more specific patient selection criteria are appropriate for X STOP patients. As discussed elsewhere, more specific criteria beyond the FDA approved indications are not feasible given the variability in patient status, patient preferences, and physician judgment.

in all three domains of the ZCQ). Under this more stringent definition, the success rate for the X STOP procedure was 47%, which is comparable to the success rates for the more invasive surgical procedures that are covered by Medicare. Using the more appropriate success rate definition of meeting threshold criteria in 2 of 3 domains of the ZCQ, the success rate for the X STOP procedure is 63.5%, again consistent with the success rates of more invasive surgical procedures covered by Medicare when these same criteria for success are applied to them.

- Concerns that the control group in the X STOP studies "failed" conservative treatment are misguided because all patients in the study, including those receiving the X STOP procedure had completed six months of conservative treatment prior to entry in the study. Thus, as one would expect in a controlled trial, all patients with LSS had been treated similarly such that when study patients were split into control and study groups, the groups were comparable.

D. FDA Approval With Conditions

In the Proposed Rule, CMS expressed concern about the fact that the X STOP was approved "only on the condition that it be used in the context of a long term (5 year) follow up study." 71 Fed. Reg. at 24073. As a threshold matter, it is important to understand that the indications for use for X STOP do not limit the product's use to only patients that are in a follow up study. Rather, SFMT agreed to take certain actions after approval including conducting a follow up study. The quoted language in the Proposed Rule seems to suggest that only study patients can receive the device, which is not accurate.

Moreover, that the FDA may have conditioned approval of the X STOP on such post approval studies is not a valid basis for CMS to refrain from granting our new technology add-on request. Indeed, we reviewed the FDA approvals of spinal implants over the past 10 years and found that all nine spinal implant approvals during that time included similar requirements such that this condition is now commonplace. Further, CMS has granted add-on status for other products that have obtained FDA approval on similar conditions. For example, we noted earlier that InFuse™ was approved for an add-on by CMS. That product was approved by the FDA on the condition of a *6 year* post approval follow up study. It would be arbitrary and capricious for CMS to withhold approval of add-on payments for the X STOP for a reason that did not prevent another product from receiving add-on payments.

E. Hospital Setting

In the Proposed Rule, CMS indicated that it has received conflicting information about the setting for use of the X STOP. In the add-on application, SFMT indicated that upwards of 90% of the X STOP procedures would be done on an inpatient basis, yet a physician at the February Town Hall meeting suggested that 90% of his use of the product is in the outpatient setting. More than likely, this was a misstatement. Based on the information available to us, we maintain that, currently, upward of 90% of the X STOP procedures are being performed on an inpatient basis.

While we have presented the current information to the best of our knowledge, SFMT does believe that the procedure can be done in the outpatient setting. It is for that very reason that we have submitted a request to CMS for a device pass-through category for purposes of the outpatient prospective payment system. As the X STOP is used more widely, it is very possible that more procedures will be done on an outpatient basis than we understand currently to be the case, but we would expect any such migration to be determined by clinicians. At the same time, we expect the procedure to be done in an inpatient setting for a number of reasons. While the procedure can be done using local anesthesia, many patients prefer to have general anesthesia for a variety of reasons (e.g., to reduce fear, anxiety, physical discomfort, etc.). When performing a procedure under general anesthesia on elderly patients, many clinicians believe an inpatient stay is warranted. For other patients, co-existing ailments may necessitate the procedure being done on an inpatient basis and this determination is made by clinicians on an individual patient basis.

In sum, the X STOP procedure is currently being done on an inpatient basis in the vast majority of cases, although that could change in the future. Even so, some beneficiaries will continue to receive the procedure on an inpatient basis such that it is appropriate for CMS to consider the X STOP for new technology add-on payments under IPPS.

VII. Conclusion

Again, SFMT appreciates the opportunity to comment on the important issues raised by the Proposed Rule. We agree with CMS that the X STOP meets the newness and cost threshold criteria for new technology add-on payments. Moreover, we believe that the X STOP also meets the substantial clinical improvement criterion, for reasons explained above and in Appendix A, and thus urge CMS to grant our add-on application effective October 1, 2006. We respectfully submit that the X STOP is precisely the type of technology that CMS should be making add-on payments for under IPPS because it provides Medicare beneficiaries with LSS with a treatment option that was not currently available prior to its FDA approval – a minimally invasive procedure that can improve the quality of life of Medicare beneficiaries and prevent them from having to undergo more invasive and complication-prone surgical procedures.

If you have questions concerning this letter, please do not hesitate to contact me at 510-337-2600. Thank you for your consideration.

Sincerely,

Kevin Sidow
President and CEO

Attachment

APPENDIX A

To the St. Francis Medical Technologies, Inc. Comment Letter on the FY 2007 Hospital Inpatient Prospective Payment System Rates

(REF: CMS FILE CODE 1488-P)

TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Centers for Medicare and Medicaid Services (CMS) currently is in the process of reviewing SFMT's application for an add-on payment for new services and technologies. As part of its proposed rulemaking process, CMS determined that the applicant met the newness and cost threshold criteria for new technology add-on payments for the X STOP Interspinous Process Decompression (IPD) System ("X STOP"). However, CMS expressed concern that the information included with the application may raise issues about substantial clinical improvement and invited comment on the following issues related to the application:

- Concerns raised by the Center for Devices and Radiological Health (CDRH) Orthopedic & Rehabilitation Devices Advisory Panel that convened in August, 2004 to review the applicant's PMA submission to FDA (i.e., concerns expressed by advisory panel members regarding patient selection, radiographic endpoints, and the clinical efficacy rate in the study population).
- Concerns raised by CMS at the Town Hall Meeting that convened on February 15, 2006 regarding the evidence from the randomized clinical study that demonstrated substantial clinical improvement among lumbar spinal stenosis (LSS) patients that received the X STOP compared to control patients who did not receive operative care.

This document summarizes the clinical evidence that supports the fact that the X STOP is a breakthrough new technology that represents a substantial clinical improvement for Medicare beneficiaries with degenerative lumbar spinal stenosis (LSS).

It is important to note that the CDRH decision to issue a PMA approval order on November 21, 2005 was based upon a determination by the agency that 1) the X STOP is safe and effective in the treatment of LSS patients when used as indicated (i.e., in LSS patients with moderately impaired physical function) and in accordance with directions for use, and 2) over the course of 15 months following the CDRH Advisory Panel, SFMT submitted additional data and analyses that adequately addressed the questions raised by the advisory panel members in August, 2004. CDRH concluded in its Summary of Safety and Effectiveness (SSE) document that "the X STOP device met the primary clinical study endpoint for success, exceeding the success rate of the control in every statistical analysis."[28]

The clinical study endpoint in the Pivotal Trial was a composite measure of success that employed the Zurich Claudication Questionnaire (ZCQ) as the primary means of evaluating health outcomes[a]. The ZCQ is a multi-item Patient-Reported Outcomes (PRO) instrument aggregated into three distinct domains (Physical Function, Symptom Severity, and Patient Satisfaction) that were separately tested and validated to measure health outcomes in LSS patients. The psychometric properties of the ZCQ (i.e., validity,

[a] The composite study endpoint included "ZCQ success" plus no additional surgery for lumbar spinal stenosis plus (for X STOP patients only) the following: maintenance of distraction (radiographic endpoint), no dislodgement of the implant, and absence of implant-related complications (See Table 1, page 11).

reliability, responsiveness) have been thoroughly assessed and well-documented elsewhere,[21, 22, 25] and the ZCQ has been reported to be the most precise, condition-specific health outcomes measure specifically validated for use in the LSS patient population[17,b]. In data and analyses submitted to FDA subsequent to the 2004 Advisory Panel meeting, SFMT clearly demonstrated that the ZCQ was, in fact, the most appropriate PRO instrument to use in the Pivotal Trial based on the study design and objectives, and the patient population[c].

It is also important to note that the CDRH convened another Advisory Panel on September 9, 2005 to discuss the design of clinical studies for spinal devices and, in response to questions regarding the selection of appropriate control groups, the panel was in general agreement that there was no *surgical* treatment in use in the United States for mild to moderate low back pain that could serve as an appropriate control. This panel of experts concurred that nonoperative care was the appropriate control therapy for this patient population, thereby validating the appropriateness of the control group selected in the design of the X STOP Pivotal Trial.

The X STOP clearly meets the "substantial clinical improvement" criterion when compared to other disease management modalities for LSS patients, as evidenced by:

- Significant improvement in (1) symptom relief; (2) physical functioning; (3) treatment satisfaction; and (4) health related quality of life when compared to a non-operative control group in a multicenter, randomized, well-controlled clinical trial.
- Comparable treatment efficacy when compared to a historical control group of patients undergoing laminectomy, while offering significant potential advantages in terms of surgical invasiveness and patient recovery.
- Lower rates of intraoperative complications compared to surgical decompression with or without concomitant fusion.
- Lower re-operation rates for unresolved stenosis systems compared to other surgical treatments.

[b] Each of the three individual domains of the ZCQ (Physical Function, Symptom Severity, and Patient Satisfaction) were separately validated by Stucki *et al.* in a LSS population at 6 months postoperatively. The clinical success definition based on combining the 3 domains of the ZCQ was further validated by Tuli *et al.* using 24-month postoperative data on the same population. A validated definition of individual patient success makes the ZCQ unique among outcomes measures. No other primary outcomes measure used in trials of spinal devices (including the ODI) has a validated criterion for determining a clinically relevant response to treatment.

[c] In February, 2006 FDA issued a comprehensive draft guidance document entitled "Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims" that clearly states that "multidomain PRO instruments can be used to support claims about a general concept if the PRO instrument has been *appropriately developed and validated to measure the important and relevant domains* of the general concept (pg 8)."

CLINICAL BACKGROUND

Overview of Patient Population and Disease

Degenerative lumbar spinal stenosis (LSS) is defined as a focal narrowing of the spinal canal, although there is some variation among investigators about the precise amount of narrowing that must occur before the canal is considered stenotic. If compression does not occur, the canal is typically described as narrow but not stenotic.[9]

The general term "spinal stenosis" can be applied to several root compression mechanisms alone or in combination:

1. Disk protrusion or herniation.
2. Osteotic overgrowth into the spinal canal or the foramina through which the roots pass laterally.
3. Vertebral slippage or spondylolisthesis.
4. *Ligamentum flavum* buckling.

The site of compression in the spinal canal may be central, lateral, or a combination of the two. Clinically, the disease manifests as neurogenic intermittent claudication (NIC) secondary to LSS, and is characterized by radicular symptoms that are exacerbated in standing, walking and other positions that place the lumbar spine in extension. In positions of flexion, such as sitting, symptoms are improved or relieved. In extreme cases, lumbar stenosis can cause cauda equina syndrome, a syndrome characterized by neuromuscular dysfunction with disturbed bowel or bladder control that can result in permanent nerve damage without immediate surgical decompression.[1, 32]

LSS symptoms may include intermittent or persistent pain in the buttocks and/or legs, limping, lack of feeling or weakness in the lower extremities, and decreased physical activity. The lack of activity may lead to obesity and general physical deterioration that may eventually result in the onset of cardiovascular and other serious health problems. Activity restrictions may also cause depression and other psychological problems.

Currently, it is estimated that as many as 400,000 Americans, most over the age of 60, may already be suffering from the symptoms of LSS.[16] This number is expected to grow as members of the baby boom generation begin to reach their 60s over the next decade.

Epidemiology data on LSS come from several studies. The annual incidence of spinal stenosis observed in a Swedish study was approximately 5 per 100,000 inhabitants.[11] From the data provided by the National Low Back Pain Study[15], researchers calculated that of all patients in the US seeking treatment for low back problems, 5% had spinal stenosis. The National Ambulatory Medical Care Survey (NAMCS) also provides data on the incidence of lumbar spinal stenosis in the US population.[10] Over the period 1989 to 1990, the diagnostic cluster for low back pain ranked fifth in frequency among categories and accounted for 2.8 percent of patient visits. Of these visits, 3.9% were classified as spinal stenosis. The National Spine Network (NSN) provides another estimate of the

prevalence of lumbar spinal stenosis using data from 17,774 patients treated at 25 centers.[7] Among these patients, 13.1% were specifically diagnosed with spinal stenosis.

The prevalence of musculoskeletal disorders and the cost to treat them led the World Health Organization and the United Nations to declare 2000-2010 to be the Decade committed to improving quality of life to people with bone and joint disease and injuries throughout the world[1].

Current Therapeutic Options

Patients with lumbar spinal stenosis are diagnosed on the basis of a combination of results of the medical history, physical examination and imaging findings (e.g., X-Ray, Magnetic Resonance Imaging [MRI], Computerized Axial Tomography [CAT], myelogram). Non-surgical management is the first-line treatment modality and includes medication to reduce swelling or to relieve pain, limits on physical activity, exercises and/or physical therapy, and a brace/corset for the lower back. If there is no improvement in the patient's condition, surgery may be necessary.[20]

The goal of treatment is to improve the patient's quality of life, and therefore the choice of intervention should be clear and based upon the individual patient's needs and desires. From an epidemiologic standpoint, however, it is often difficult to make direct comparisons of the effectiveness of these treatment options due to the wide variations of disease state and symptom severity within the LSS patient population. Within the context of clinical trial design, effectiveness comparisons between different interventions can only be made if the interventions are clinically appropriate based on the inclusion and exclusion criteria used to define the study population, and this specificity enables an appropriate answer to the primary research question posed within the study.[29] At this time, the only consensus within the medical research community is that more study in this area is needed.

Lumbar spinal decompression, decompression with laminectomy, and fusion are the surgical treatments of choice for central spinal stenosis, lateral canal stenosis and recurrent stenosis, respectively.[18] Conservative decompressive procedures may include fenestration, laminotomy, selective decompression and lamiarthectomy; such procedures are carried out with the goal of minimizing disruption to the integrity of the laminae, facet joints, and interspinous ligaments. However, the need to achieve adequate surgical decompression limits the number of LSS patients who might be considered appropriate candidates for these procedures. The standard decompressive lumbar laminectomy involves a midline incision over the involved levels of the spine, dissection down to the spinous processes and progressive removal or "unroofing" of the posterior elements of the lumbar canal (spinous processes, laminae and pedicles), as well as removal of thickened ligamenta flava. Wide decompressive laminectomy procedures are the most invasive and are often combined with medial facetectomy and foraminotomy; such procedures may lead to mechanical failure of the spine and chronic pain syndrome and are therefore often combined with fusion.[9]

Decompressive laminectomy is considered a relatively invasive surgical procedure, especially when accompanied by a fusion. The risks of laminectomy depend on the number of levels to be decompressed, concomitant medical problems, difficult anatomy as a result of scarring from previous operations or a markedly stenotic canal that may require extensive bone removal and dissection, as well as the overall risks imposed by general anesthesia. Potential complications of the standard decompressive laminectomy include wound infection, hematoma formation, dural tears with subsequent cerebrospinal fluid leaks and risk of meningitis, nerve root damage with resultant neurological deficit or paralysis, and the potential for creating postoperative spinal instability. Surgical blood loss is generally well tolerated, but transfusion may be required.

The complication rates associated with decompressive surgeries can vary depending on the type of procedure performed. Deyo *et al.* reported the complication rates among LSS Medicare patients nationwide treated surgically with and without fusion.[4] In their study, there were 10,079 hospitalizations for patients who underwent a laminectomy without fusion; complication and mortality rates in this group of patients were 9.7% and 0.8%, respectively. Among 589 hospitalizations for patients who underwent laminectomy with fusion, the complication and mortality rates were 14.9% and 1.0%, respectively. In addition, 47% of the fusion patients and 18% of the non-fusion patients required a blood transfusion.

All of these treatment options represent a continuum of care that begins with conservative nonoperative therapy, jumps to progressively invasive decompressive surgical procedures and eventually ends with decompressive laminectomy and fusion surgery. Each of the interventions is appropriate for different disease stages and should be selected on the basis of a risk-benefit analysis of the most clinically appropriate care for an individual patient.

Role of X STOP in the Continuum of Care

Recently, the need to fill the gap in the continuum of care that required patients to make the leap from conservative therapies to invasive surgery, has led to the development of devices designed to relieve symptoms of LSS through Interspinous Process Decompression (IPD). IPD is a minimally invasive surgical procedure in which a spacer is inserted between spinous processes and placed posterior to neural elements, leaving intact the protective lamina and minimizing the risk of neural injury. There are several interspinous process spacers currently undergoing development and/or clinical testing (i.e., the Coflex [Paradigm Spine], the Diam [Medtronic], the Wallis [Abbott Spine], and the X STOP [St. Francis Medical Technologies]) but the X STOP System is the only IPD device currently marketed in the US. The X STOP implant is unique in that it is not fixed to any bony structure. With use of the X STOP, motion is preserved thereby allowing unrestricted motion in flexion, lateral bending and axial rotation. The X STOP IPD procedure is currently the only surgical option for patients who cannot tolerate general anesthesia, as the procedure can be performed using only local anesthesia and typically can be completed in less than one hour.

X STOP IPD is now a clinically proven, minimally invasive treatment alternative for moderately impaired LSS patients that fills the gap in the continuum of care. Moderately impaired LSS patients are most often managed conservatively with a spectrum of nonoperative therapies. Those who are not satisfied with their degree of symptom relief from conservative medical management but who are either unwilling or unable to undergo invasive surgical decompressive procedures often endure diminishing quality of life and an increasingly sedentary lifestyle over a period of several, or many, years. X STOP IPD represents an effective, middle-of-the-road alternative for these patients that does not compromise future surgical options, yet has been proven superior to conservative care in providing symptom relief and improved quality of life.

Product and Technology Overview

The X STOP is an interspinous process spacer that is placed between the spinous processes to limit extension of the symptomatic level(s), yet allow flexion, axial rotation and lateral bending (Figure 1). This provides a potential alternative to conservative and surgical treatments.

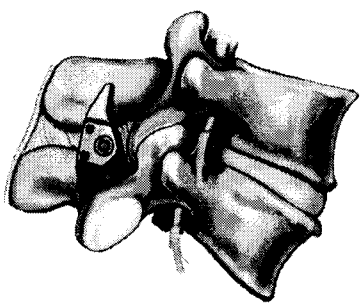
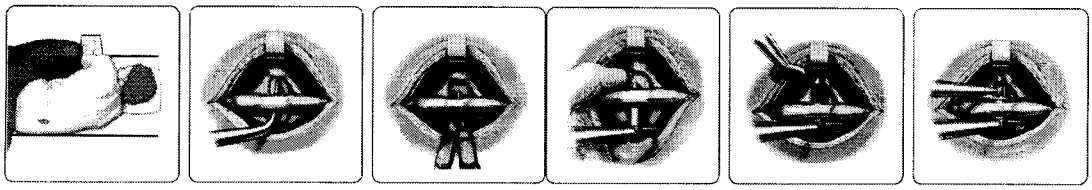


Figure 1: X STOP implant inserted between spinous processes

Patients may be operated on under local anesthesia with light intravenous sedation, placed in a lateral decubitus position (Figure 2). A 4 to 8 cm mid-line incision is made exposing the spinous processes at the appropriate disc level, which is confirmed radiographically. The supraspinous ligament is preserved, which is important in the prevention of postoperative kyphosis, and also serves to stabilize the implant. The interspinous ligament is pierced, but retained, and the implant is placed between the spinous processes. The spinous processes are not modified to allow implantation but in cases where hypertrophied facets protrude posteriorly, they should be trimmed without compromising functional integrity.



2a 2b 2c 2d 2e 2f

Figure 2: (a) Patient is placed in lateral decubitus position; (b) interspinous ligament is dilated; (c) sizing distractor is inserted to determine implant size; (d) mainbody spacer is inserted; (e) adjustable wing is attached to mainbody with wing insertion instrument; (f) wing assembly is adjusted to fit snugly against lateral surface of spinous processes and locking screw is tightened with hex head screwdriver.

Narrowing of the spinal canal and neural foramina during extension is widely believed to be the source of neural compression and subsequent pain in LSS patients. *In vitro* biomechanical testing has demonstrated that X STOP placement significantly increases the spinal canal and neural foramina areas of the treated level(s) during extension, and does not significantly affect the areas of the untreated level(s).[27] These data are consistent with the results from an *in vivo* clinical radiographic study using standing MRI, where the cross-sectional area of the dural sac and exit foramina were shown to increase following X STOP implantation, without causing changes in posture.[19] Additional biomechanical testing has demonstrated that X STOP placement significantly decreases the intervertebral disc pressure and facet loading at the treated level(s), and does not significantly affect the pressure or loading of untreated levels.[14, 23,31]

Regulatory Status and Overview of FDA Review

The X STOP IPD System received FDA approval through the Premarket Approval (PMA) process on November 21, 2005. According to the PMA Approval Order, the device is indicated for treatment of patients aged 50 or older with neurogenic intermittent claudication (NIC) secondary to a confirmed diagnosis of lumbar spinal stenosis, with X-Ray, magnetic resonance imaging (MRI), and/or computed tomography CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal narrowing. It is indicated for patients with moderately impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, with or without back pain, and who have undergone at least six months of non-operative treatment. The approval order states that the X STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

It is important to note that the CDRH decision to issue the PMA Approval Order was based upon a determination by the agency that 1) the X STOP is safe and effective in the treatment of LSS patients when used as indicated (i.e., in LSS patients with moderately impaired physical function) and in accordance with directions for use, and 2) that SFMT submitted additional data and analyses that adequately addressed the questions raised by CDRH advisory panel members in August, 2004[d].

[d]A CDRH Orthopedic and Rehabilitation Devices Advisory Panel meeting was convened on August 31, 2004 to review the X STOP PMA application. The Panel recommended to FDA, by a vote of 5-3, that the

Over a 15-month period from the time of the August, 2004 Advisory Panel meeting to the issuance of the PMA Approval Order, SFMT worked closely with FDA to address the concerns of the Advisory Panel. Data from additional analyses performed by the Sponsor were provided that clearly identified the subset of patients from within the study population that were most likely to benefit from the X STOP. The group of patients comprised those with moderately impaired physical function at baseline (defined as patients having baseline Physical Function scores > 2.0 using the ZCQ). As a result, the Indications for Use statement in the product labeling was revised to specify this patient population. CDRH concluded in its Summary of Safety and Effectiveness (SSE) document, issued at the time of the PMA Approval Order, that "the X STOP device met the primary clinical study endpoint for success, exceeding the success rate of the control in every statistical analysis." This statement was applicable not only to the subset of indicated patients, but to the entire study population within each study site and in aggregate across all nine study sites[e].

In addition, SFMT submitted *in vivo* clinical radiographic data to FDA that definitively supported the *in vitro* biomechanical testing of the X STOP mechanism of effect on the lumbar spine, the results of which had previously been included in the company's PMA application and presented to CDRH's Advisory Panel. The results of the *in vivo* clinical radiographic study were subsequently published by the research group from University of Aberdeen who undertook the study.[19]

The PMA Approval Order issued by FDA requires SFMT to conduct a "Condition of Approval" (CoA) study to evaluate the long-term safety and effectiveness of the X STOP in patients who received the device under the Investigational Device Exemption (IDE)[f]. Within the broader context of FDA's regulatory authority, it is noteworthy that CoA clinical studies are commonly imposed upon spinal implant manufacturers as a condition of PMA approval. Over the last 10 years, FDA has issued 9 PMA Approval Orders for spinal implants, all of which required CoA studies of at least 5 years duration.

PMA be found not approvable citing concerns with the need to identify the patient population most likely to benefit from the device, clinical effectiveness rates, and the need to provide objective radiographic data to confirm the device's *in vivo* mechanism of effect.

[e] Overall treatment success in the X STOP and control groups was 44% and 5%, respectively, in the entire study population ($p < 0.001$). Overall treatment success within the *indicated* population was 54% and 6% in the X STOP and control groups, respectively ($p < 0.001$).

[f] The conditions of approval imposed by FDA also requires a new clinical study to analyze long-term safety and effectiveness data on a patient population who meet enrollment criteria based upon the approved Indications for Use in the product labeling. Consistent with FDA's guidance on postmarket CoA studies, SFMT is required to report the results of both studies to the FDA every six months until the studies are completed. Postapproval requirements imposed by FDA *commonly* include one or more CoA studies and may also include additional requirements. For example, in the PMA Approval Order issued to the manufacturer of InFUSE™ Bone Graft, the FDA's conditions of approval required the manufacturer to obtain 6 year postoperative data from a "statistically justified" number of patients implanted with the device—the patients were to be selected from either the IDE population, a population of postapproval implant patients or a combination of both (the protocol to be provided in a post-approval report). In addition, the FDA required the manufacturer to provide retrieval analyses of all explants (not limited to study patients) for 6 year period.

Following the August 31, 2004 Advisory Panel meeting, the CDRH convened another Orthopedic & Rehabilitation Devices Advisory Panel to discuss the design of clinical studies for spinal devices. This meeting came to order on September 9, 2005. The FDA framed questions for the panel members to consider with regard to intended study population, potential control groups, appropriate study endpoints, and other issues concerning the methodological challenges associated with designing clinical trials for spinal devices that are intended to treat patients with mild to moderate symptoms arising from spinal disorders. In response to questions regarding the selection of appropriate control groups, the Panel was in general agreement that there was no *surgical* treatment in use in the United States for mild to moderately symptomatic patients that could serve as an appropriate control in these types of trials. This panel of experts concurred that nonoperative care was the appropriate control therapy for this patient population, thereby validating the appropriateness of the control group selected in the design of the X STOP Pivotal Trial.

Other highlights from the September, 2005 panel meeting and panel members' recommendations are as follows:

- The most important metric for outcomes is patient satisfaction within the context of the treatment provided. In the medical literature, patient satisfaction has been described as the gold standard for measuring outcomes.[30]
- Appropriate thresholds of clinical significance to define success in individual patients must be validated. The large difference in risk between current operative treatment and nonoperative therapy must be taken into account.
- The ethical issue involved with randomly assigning a patient with mild to moderate symptoms to invasive and risky surgical procedures must be considered in designing clinical trials.
- Investigational and control therapies with comparable risks and benefits must be selected. For interspinous spacers, nonoperative care is an appropriate control since neither would expose patients to the risks of neural injuries and general anesthesia and both keep future treatment options open.
- With regard to mechanism of action endpoints (e.g., objective radiographic criteria) panel members believed they had some value but that patient-oriented outcomes were more important.

REVIEW OF SCIENTIFIC AND CLINICAL LITERATURE

1992 – Meta-Analysis of Spinal Stenosis Literature

A comprehensive meta-analysis conducted by Turner *et al.*[26] serves as the basis for interpreting clinical outcomes associated with traditional surgical treatments for spinal stenosis. This literature review included 74 peer-reviewed manuscripts and concluded that a mean of 64% of lumbar stenosis patients reported good-to-excellent results at five years postoperatively.

1997 – Pilot Study

Early in 1997, a 10-patient clinical pilot study of the X STOP implant was conducted. Outcomes were assessed using the Zurich Claudication Questionnaire (ZCQ), (also referred to as the Swiss Spinal Stenosis [SSS] survey or the Brigham Spinal Stenosis [BSS] questionnaire). The ZCQ was chosen because it is the only condition-specific health outcomes instrument specifically designed and validated for lumbar spinal stenosis patients. Eight out of 10 patients showed significant clinical improvement in the physical function and symptom severity domains of the ZCQ. On the basis of these results, a prospective randomized multi-center IDE clinical study comparing X STOP surgery to conservative (nonoperative) treatment was approved by FDA.

2000 – IDE Prospective Randomized Multicenter Study

In a prospective, randomized controlled trial, 191 patients (100 X STOP, 91 controls) were enrolled and treated at 9 centers in the US. Enrollment in the IDE Pivotal Trial began in June, 2000 and in June, 2001 enrollment was completed. The objective of the study was to evaluate the safety and effectiveness of the X STOP implant compared to conservative (nonoperative) treatment for the management of symptoms of neurogenic intermittent claudication (NIC) secondary to LSS. All patients underwent clinical and radiographic evaluations at baseline and at 6 weeks, 6 months, 12 months and 24 months postoperatively. Quality of life outcomes were assessed using two well-validated outcomes instruments: the ZCQ, a condition-specific questionnaire and the SF-36, a general heath measurement instrument. The primary effectiveness endpoint was overall treatment success at the 24-month follow-up (Table 1).

Table 1: Components of Overall Treatment Success

Criterion	X STOP	Control
ZCQ Success*: • improvement in Physical Function (by > 0.5 pts), and • improvement in Symptom Severity (by > 0.5 pts), and • "Satisfied" or "Somewhat Satisfied" (< 2.5 pts)	X	X
No additional surgery for lumbar stenosis	X	X
Maintenance of distraction	X	
No dislodgement of the implant	X	
Absence of implant-related complications	X	

*NOTE: The cutoff values for each domain of the ZCQ were validated by Stucki *et al.* prior to the start of the Pivotal Trial.

The rate of operative and device-related complications associated with the X STOP was low (4% and 3%, respectively), and no complications resulted in long-term clinical sequelae. In the X STOP group, 6 patients went on to laminectomy and had the X STOP removed whereas in the control group, 24 patients underwent laminectomy (6% vs. 26%, respectively).

Two-year study results demonstrated a clinically and statistically significant difference favoring the X STOP over nonoperative care. In the patient population for whom the X STOP is indicated, 64% of the X STOP patients reported that their symptoms were significantly improved compared to 17% of the control patients. With respect to physical function, 66% of X STOP patients reported significant improvement compared to 17% of control patients. Among X STOP patients, 73% were satisfied or very satisfied with their treatment compared to 24% of the control group patients. Overall treatment success in the X STOP group was 54% compared to 6% in the control group. The results for the indicated patient population, as well as the entire study population, are summarized in Table 2 below[g].

Table 2: Treatment Success at 24 Month Follow-Up*

Outcome Parameter	Evaluable Population†		Indicated Population††	
	X STOP	Control	X STOP	Control
	n/N (%)	n/N (%)	n/N (%)	n/N (%)
ZCQ Success Rate by Domain				
Physical Function	**55%** (53/96)	**14%** (12/87)	**66%** (48/73)	**17%** (11/66)
Symptom Severity	**58%** (56/96)	**17%** (15/87)	**64%** (47/73)	**17%** (11/66)
Patient Satisfaction	**71%** (68/96)	**32%** (28/87)	**73%** (53/73)	**24%** (16/66)
Percent of Patients Meeting all 3 ZCQ Criteria				
ZCQ Success	**47%** (45/96)	**5%** (4/87)	**56%** (41/73)	**6%** (4/66)
Overall Treatment Success				
Overall Success	**44%** (41/94)	**5%** (4/87)	**54%** (38/71)	**6%** (4/66)

*Differences between X STOP and control groups were statistically significantly different in all comparisons (P-values determined using Fisher exact test, level of significance < 0.05)

†Evaluable population was defined as all treated patients who survived through 24 month follow-up

††Indicated population was defined as all treated patients with baseline Physical Function scores > 2.0 who survived through 24 month follow-up; this is the LSS population for whom the device is intended for use, per FDA approved product labeling.

Overall quality of life was also examined using the SF-36 as a secondary effectiveness endpoint. The mean scores for the Physical Component Summary (PCS) and Mental Component Summary (MCS) for the X STOP and control patients comprising the indicated population, at baseline and 24 month follow-up, are shown in Table 3. There were no statistically significant differences in mean baseline SF-36 domain scores between the X STOP and control groups (using an ANOVA, $p<0.05$). At the 24-month follow-up, as would be expected, there was no statistically significant difference in the MCS mean change score between the two groups. However, the mean change score for the PCS at the 24-month follow-up was statistically significantly higher in the X STOP group compared to the control group. The results of the SF-36 Health Surveys

[g] For a detailed explanation of the Indications for Use, please refer to Regulatory Status and Overview of FDA Review section, page 8.

demonstrated the superiority of X STOP over control, and were consistent with the results of the condition-specific ZCQ.

Table 3: SF-36 Domain Scores at Baseline and 24 Month Follow-up (Indicated Population)

Domain*	X STOP			Control		
	Preop	24 mo	% Improved	Preop	24 mo	% Improved
Physical Component Summary (PCS)	26.9	39.6	**47%**	26.9	29.1	**8%**
Mental Component Summary (MCS)	49.6	53.9	**9%**	48.9	52.5	**7%**

*The PCS and MCS are each comprised of the eight SF-36 domains, but are weighted differently. The PCS is weighted more heavily toward the Physical Functioning (PF); Role Physical (RP); Bodily Pain (BP), and General Health (GH) domains, whereas the MCS is weighted more heavily toward the Vitality (VT), Social Functioning (SF), Role Emotional (RE), and Mental Health (MH) domains.

In the Pivotal Trial, more than a third of the patients suffered from a degenerative spondylolisthesis up to grade 1 (out of 4). In a recently published study of this spondylolisthesis cohort, Anderson *et al.*[2] reported that, at all postoperative intervals, statistically significant improvement in ZCQ and SF-36 scores was seen in the X STOP treated patients, but not in the nonoperative control patients. Within this cohort, overall clinical success rates at the 24 month follow-up were 63.4% in the X STOP group compared to 12.9% in the control group. This important finding substantiates the validity of X STOP implantation as a minimally invasive treatment alternative for LSS patients with degenerative spondylolisthesis, who generally have no option but an instrumented spinal fusion—a choice that may not be appropriate for many older patients with comorbid conditions.

Long-term outcomes data from a subset of patients enrolled in the Pivotal Trial have been analyzed. The manuscript describing these results has been accepted for publication in a peer-review journal[13] and previously submitted to CMS for review. In this series of 18 X STOP patients at one clinical center, pre- and postoperative ODI scores were obtained over approximately 4 years follow-up (minimum 43 months, average 51 months).[h] Average pre- and postoperative ODI scores were 45 and 15 in this group, respectively. Using a 15-point improvement in ODI score from baseline as a success criterion, 78% (14/18) of X STOP patients were successful at 4 years postoperatively.

2003 – Analysis of spinal surgical cohort data.

The design of a randomized controlled trial that compares the X STOP IPD procedure with traditional surgical treatment of lumbar spinal stenosis is a very challenging task. X STOP represents the missing ring of the chain of care and it would be inappropriate to utilize a more invasive control that is standard of care for a later stage of LSS if X STOP

[h] The ODI was utilized with this patient series (rather than the ZCQ), as part of a larger retrospective study in which pre- and postoperative ODI data and procedural cost data were analyzed and compared to a cohort-matched control group of laminectomy patients; the ODI is routinely administered to all spine patients at this center and therefore was the appropriate outcomes measure for the retrospective study. The data from this study were presented at the 2006 Spine Arthroplasty Society (SAS) meeting in Montreal, Canada[12].

is intended for an earlier stage of degeneration. The panel members at the Orthopedic & Rehabilitation Devices Advisory Panel Meeting held in September, 2005 were in general agreement that there was no surgical treatment in use in the US for mild to moderately symptomatic patients that could serve as an appropriate control in randomized trials of minimally invasive spinal devices.

Despite the difficulties, we have researched the performance of X STOP versus laminectomy patients. Katz *et al.* conducted an analysis on a surgical cohort of 197 LSS patients who underwent laminectomy with the purpose of providing the X STOP investigators with comparison data using the ZCQ patient questionnaire and the same definition of individual patient success as was used in the X STOP Pivotal Trial.[25] This surgical cohort therefore represents a non-randomized historical control for the X STOP clinical trial. The study population comprised patients who underwent laminectomy during the time period from 1989 until 1993 and who were followed-up for 24 months. Changes in ZCQ scores from baseline to the 24-month follow-up were calculated in the same manner as was done in the X STOP Pivotal Trial. Individual patient success was achieved when three validated criteria were met: 0.5 point improvement from baseline Physical Function score, 0.5 point improvement from baseline in Symptom Severity score, and a Patient Satisfaction rating of "satisfied" or "very satisfied" at the 24-month follow-up.

Two years after the surgery, 63% of the laminectomy patients reported that their symptoms were significantly improved. Regarding physical function, 59% of patients reported significant improvement. With respect to treatment satisfaction, 72% of patients were satisfied or very satisfied with their treatment. When all three criteria were met, the success rate in this surgical cohort was 47%.

When compared to the results from all evaluable X STOP patients from the Pivotal Trial, the results from the surgical cohort are quite similar (Figure 3). The success rates were 47% in the surgical cohort compared to 44% in the evaluable X STOP patient population.

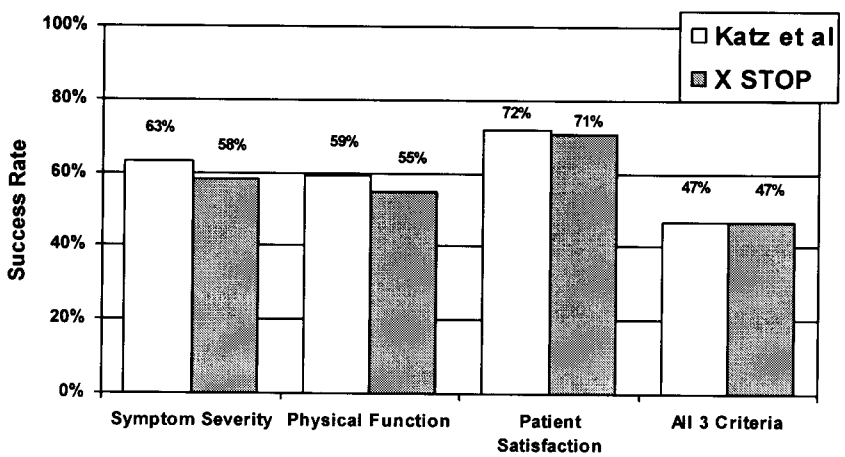


Figure 3: X STOP Pivotal Trial Patients (Evaluable Population) vs. Katz LSS Laminectomy Cohort

Similarly Zucherman *et al.*[33] reported on a group of 6 X STOP and 22 control patients in the Pivotal Trial who underwent a laminectomy during the study. After an average of 1.2 years follow-up, the success rates for the Symptom Severity, Physical Function, and Patient Satisfaction domains were 57%, 64%, and 54% respectively; 43% of patients met all three criteria and were considered a clinical success. Likewise, Fokter *et al.*[8] reported on 58 laminectomy patients with an average of 27 months follow-up. The Symptom Severity, Physical Function, and Patient Satisfaction domain success rates were 64%, 55%, and 59% respectively; 43% met all three domain criteria in this series.

These results suggest that the X STOP can be a viable alternative to laminectomy in the LSS population, particularly those patients who are moderately impaired and dissatisfied with their nonoperative management but unwilling to proceed to laminectomy. The X STOP procedure can be performed under local anesthesia, is associated with fewer, and less severe complications compared to more invasive surgical options, and comparable results may be achieved with quick recovery time.

INTERPRETING OUTCOMES FROM THE X STOP PIVOTAL TRIAL

The results of the Pivotal Trial clearly and significantly demonstrated that the X STOP device significantly improved health status when a group of LSS patients who underwent X STOP IPD surgery was compared to a group of patients who did not. The X STOP device met the primary clinical study endpoint for success, exceeding the success rate of the control in every statistical analysis. In 2005, a panel of medical experts[i] concluded that nonoperative therapy is, indeed, the appropriate control therapy in randomized trials of minimally invasive devices such as the X STOP device thereby validating the study design selected for the Pivotal Trial.

Nevertheless, some have argued that patients in the control group had "failed" conservative treatment and therefore did not represent an appropriate group to which comparisons could be made to judge whether X STOP IPD treatment effects were beneficial. Others have further argued that the success rates reported for the X STOP cohort were "lower than expected" and therefore question the effectiveness of X STOP IPD. These criticisms represent a misinterpretation of the study design and results, and merit further discussion.

Selection of Control Group

All patients enrolled in the Pivotal Trial, whether randomly assigned to the X STOP group or the control group, were required to have completed six months of conservative treatment prior to entry. The purpose of this entry criterion was to assure that patients enrolled in the study had persistent LSS symptoms that required treatment and were not suffering from an acute episode. These were not patients who had "failed" prior treatment. Indeed, references in the medical literature to those patients who "fail" conservative care are typically made only when discussing the subgroup of conservatively treated patients who ultimately undergo laminectomy surgery.[5, 24] In Turner's meta-analysis[20], the mean time of symptom duration for patients electing to undergo a decompressive laminectomy was 4.3 years (51.3 months), confirming the slow but progressive debilitating effects of LSS compared to other spinal conditions such as HNP and DDD.

There is ample evidence from the Pivotal Trial to suggest that control group patients had not failed treatment at study entry. Defining "failed treatment" as "progression to surgery," there were only 24 patients in the control group who went on to laminectomy surgery during the course of the study. This represented 29% (24/87) of the "evaluable" control group patients enrolled. Additionally, 32% (28/87) of control group patients were "very satisfied" or "somewhat satisfied" with their treatment at the 24 month follow-up.

If, however, one were to disregard this evidence and assert that control group patients had "failed" conservative treatment, this assertion would also hold true for patients assigned to the X STOP group since all patients enrolled into the study had to satisfy the same

[i] Orthopedic & Rehabilitative Devices Advisory Panel to FDA, convened September 9, 2005.

entry criterion (that is, all patients had to have "completed six months of conservative treatment" prior to study entry). In this scenario, the two study groups are still entirely comparable and the conclusion that could be drawn is that LSS patients who have "failed" conservative treatment and are subsequently treated with X STOP IPD surgery will fare significantly better than patients who are not provided the X STOP treatment option—no matter what criteria are used to define a successful outcome.

To summarize, the majority (71%; 62/87) of patients assigned to the control group had not "failed" treatment—only 29% (25/87) progressed to laminectomy during the 24 month follow-up period of the study. Furthermore, a substantial proportion of control group patients were satisfied with their treatment (32%; 28/87) at the 24 month follow-up.

Clinical Effectiveness Results

In order to determine whether clinical effectiveness rates are "lower than expected," it is important to understand the frame of reference, as well as the set of expectations, by which effectiveness rates are being evaluated. For the X STOP Pivotal Trial, there was no "target" success rate that had to be achieved to satisfy a clinical effectiveness requirement—rather, the success rates hypothesized in the study protocol (60% and 37.5% for the X STOP and control groups, respectively[j]) were for sample size planning only. Since there was no "target" effectiveness rate, and the primary study endpoint was overall clinical success as measured by the ZCQ, this patient-reported health outcomes measure is an appropriate "frame of reference" that must be fully understood in order to interpret key study findings.

The ZCQ has been reported to be the most precise, condition-specific health outcomes measure specifically validated for use in the LSS patient population.[17] The psychometric properties of the ZCQ (i.e., validity, reliability, responsiveness) have been thoroughly assessed and well-documented elsewhere.[21, 22] In designing the ZCQ, the authors intended that the tool be utilized as a complement to more general health status instruments that comprehensively assess physical, emotional, and social dysfunction.[21] More specifically, the authors intended that the three "scales," or domains of the ZCQ would be used to measure three distinct concepts—symptom severity, physical function, and patient satisfaction—that were felt to reflect the goals of intervention in treating LSS patients. As such, each of the scales, or domains, was separately validated.

At the time the Pivotal Trial was initiated, a validated definition of "clinical success" based on the ZCQ was not available. This situation is not uncommon with health outcomes measures, which are designed primarily to detect treatment effects regarded as clinically meaningful. As an example, the Oswestry Disability Index (ODI) is commonly

[j] The hypothesized delta between success rates in the X STOP and control groups was 22.5%. The actual delta between success rates was 48% in the Pivotal Trial (54% vs. 6% in the X STOP and control groups, respectively, for the indicated patient population).

associated with a success definition of a "15-point change from baseline," but this definition has never been validated.[6]

The Sponsor therefore developed a success definition using the ZCQ based on the most conservative approach possible. The success definition used in the Pivotal Trial required that a patient meet success criteria in all three domains of the ZCQ to qualify as a success (i.e., 0.5 pt. improvement in Symptom Severity *and* 0.5 pt. improvement in Physical Function *and* a Patient Satisfaction score < 2.5) [k]. Using this stringent definition, the results from the Pivotal Trial demonstrated that 1) clinically and statistically significant improvements in Symptom Severity and Physical Function resulted from X STOP treatment 2) a high proportion of X STOP patients were satisfied with the treatment received, and 3) overall success rates were statistically significantly better in the X STOP group when compared to the control group (as previously shown in Table 2).

Based on new research findings, we can now demonstrate that the original definition of clinical success employed in the Pivotal Trial was, in fact, too stringent. Using the ZCQ, Tuli *et al.*[25] recently tested various case definitions of successful outcome for LSS patients in order to develop a success definition based on a robust scientific approach that employed ROC methodology[l]. The authors determined that a success definition requiring success in "3 of 3" ZCQ domains (the definition used in the Pivotal Trial) is highly specific in detecting true success but lacks sufficient sensitivity to adequately discriminate true failures (ROC analysis: sensitivity = 0.62; specificity = 0.98). In other words, they determined that patients who had a poor outcome, as judged by an external standard, would be incorrectly classified as "clinical successes" only 2% of the time (specificity = 0.98). However, only 62% of patients who indeed have a successful outcome would be classified as a "clinical successes" when applying this definition. Instead, the case definition that offered the best balance of sensitivity and specificity required success criteria be met in "2 of 3" domains (ROC analysis: sensitivity = 0.81; specificity = 0.87).

The results from the Pivotal Trial have been analyzed utilizing the method described by Tuli *et al.* When "2 of 3" domains is applied as the success definition, success rates in the X STOP and control groups were 63.5% and 18.4%, respectively (Table 4).

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[k] These cut-off values were adapted from the research findings of Stucki *et al.*, who established that the "minimum clinically important difference" for Symptom Severity, Physical Function and Patient Satisfaction were 0.48, 0.52, and 2.5, respectively. Based on these findings, the authors defined the "minimum clinically important difference" (MCID) for Symptom Severity and Physical Function as 0.5 and 0.5, respectively.

[l] Receiver operating characteristic (ROC) methodology involves the construction of curves based on computing sensitivity and specificity of a range of measured changes in health status. Area under the curve (AUC) is used to indicate the accuracy with which measured changes in health status correspond to patients' judgments of important changes in health status.

Table 4: The Effect of Multiple Criteria Using the ZCQ – X STOP Pivotal Trial (Evaluable Population)

Criteria Using to Define ZCQ Success			% Meeting each Criterion		P-value
# of Criteria	Sensitivity	Specificity	X STOP (N = 96)	Control (N = 87)	
Any 1 criterion	0.96	0.63	74.0%	40.2%	<0.001*
Any 2 criteria	0.81	0.87	63.5%	18.4%	<0.001*
All 3 criteria	0.62	0.98	46.9%	4.4%	<0.001*

* Indicating a level of significance < 0.05 (P-values determined using the Fisher exact test)

Applying the appropriate success criteria to other laminectomy patient cohorts evaluated using the ZCQ[m], similar results are obtained (Table 5). Success rates in every population exceeded 60% (range: 61.5% to 64.8%) when "2 of 3" domains was the success definition. Moreover, these results are also consistent with success rates reported in the literature for laminectomy populations where "global" ratings (e.g., "excellent, good, fair, or poor") are typically used to measure health outcomes.[3]

Table 5: The Effect of Multiple Criteria on Success Outcomes

# of ZCQ Criteria Required to Qualify as "Success"	Laminectomy Population			X STOP Evaluable Population
	Katz (N = 197)	Fokter (N = 58)	Pivotal Trial (N = 28)	Pivotal Trial (N = 96)
Any 1 criterion	82.1%	70.7%	67.9%	74.0%
Any 2 criteria	64.8%	63.8%	64.3%	63.5%
All 3 criteria	47.4%	43.1%	42.9%	46.9%

In summary, when success in "2 of 3" ZCQ domains is required to declare a patient a "clinical success," the X STOP success rate (63.5%) is consistent with laminectomy results for three separate cohorts (ranging from 61.5% to 64.8%). When the original criteria of success in three ZCQ domains are used, the X STOP success rate (46.9%) remains consistent with the 43% to 47% range of success rates seen in the laminectomy cohorts. These success rates are not abnormally or unusually low using this stringent success definition and are, in fact, consistent with the outcomes of the current standard for LSS treatment.

We assert that the results of the Pivotal Trial and a comparative analysis of the literature provide irrefutable evidence that X STOP IPD surgery is an effective treatment option for patients who suffer from LSS, and that X STOP IPD surgery represents a substantial clinical improvement over other, currently available treatment options. Important points to consider are the following:

- The results of the Pivotal Trial demonstrated that treatment with the X STOP device is significantly superior to conservative treatment, the appropriate comparison therapy.

- Substantial proportions of X STOP patients experienced clinically and statistically significant improvement in Symptom Severity and Physical Function when

[m] The laminectomy patient cohorts include the 197 laminectomy patients described by Tuli *et al.*[25] and the series of 58 laminectomy patients described by Fokter.[8]

compared to baseline, and the majority of patients were satisfied with their treatment.

- A validated "composite" definition of success that represents the most appropriate balance of sensitivity and specificity is success in "2 of 3" ZCQ domains—the methodology employed in the Pivotal Trial to define success was more stringent.

- The success rates reported for X STOP patients in the Pivotal Trial are comparable to results for laminectomy cohorts when the *same* definitions of successful outcome are used.

- X STOP results are consistent with the ranges of success rates reported for similar surgical patient cohorts when the same criteria are applied. Success rates using "3 of 3" criteria are not abnormally or unacceptably low in the X STOP and laminectomy patient cohorts. Rather, this success definition lacks the sensitivity to detect meaningful improvement. The success definition of "2 of 3"domains has been validated as the most clinically relevant method of defining success and, when applied to these same X STOP and laminectomy cohorts, success rates exceeding 60% were consistently demonstrated.

CONCLUSIONS

Lumbar spinal stenosis can be viewed as a disease continuum characterized by progressively increasing disability and pain. The goal of treatment is to improve quality of life for the LSS patient. Many patients, who are generally older, choose to endure their symptoms rather than undergo surgery due to its attendant risks. In the treatment continuum, there is a huge gap between nonoperative care and surgical decompression in terms of invasiveness. X STOP fills this gap, offering relief from symptoms through a safe, effective, and minimally invasive procedure for patients that do not gain adequate benefit from nonsurgical therapies but are not impaired severely enough to elect invasive surgery.

Unlike laminectomy, the X STOP procedure does not require general anesthesia, making it a more viable option for those with lumbar spinal stenosis who cannot tolerate general anesthesia as a result of their age or other health conditions. A low-risk alternative to current treatments, the X STOP procedure is also completely reversible so it can be used as a first line surgical approach without compromising any future therapeutic alternatives, including laminectomy. The X STOP is a procedure that can be performed on an inpatient or outpatient basis, as dictated by the patient's medical condition (e.g., age, presence of comorbidities, etc.) and the medical judgment of the attending physician. The procedure itself typically takes less than one hour and many patients are able to walk out of the hospital the same day due to rapid recovery and minimal risk of systemic and local complications. Additionally, as it is not fixed to any bony structures, X STOP does not result in fusion.

The results of clinical studies demonstrate that the X STOP offers a major clinical improvement for LSS patients. The X STOP is significantly better than nonoperative treatment—rather than simply treating symptoms, the X STOP acts to prevent spinal canal and foramina narrowing in extension thereby eliminating the cause of symptoms. As demonstrated by the results of a large, multicenter randomized controlled trial—the gold standard in clinical research—quality of life is significantly improved in X STOP patients compared to patients treated with conservative, nonoperative therapy. In comparison to decompressive laminectomy surgery, the X STOP is a minimally invasive low-risk treatment alternative associated with quality of life outcomes comparable to those seen with laminectomy.

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187

PARTNERS

Courier

June 12, 2006

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An integrated health care system founded by Brigham and Women's Hospital and Massachusetts General Hospital

Attention: CMS-1488-P

Dear Dr. McClellan:

Partners HealthCare System, Inc. (Partners) is pleased to comment on the Proposed Rule for the Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates as published in the April 25, 2006 Federal Register, on behalf of its member hospitals:

Institution	Provider Number
Brigham & Women's Hospital	220110
Faulkner Hospital	220119
Massachusetts General Hospital	220071
Newton-Wellesley Hospital	220101
North Shore Medical Center	220035
Shaughnessy-Kaplan Rehabilitation Hospital	222026

Proposed Changes to the DRG Payment System

Partners HealthCare supports changes in a classification system that better differentiates severity of illness and resource intensity and a weighting methodology that more closely aligns payment accuracy across all DRGs. As a matter of policy, we support MedPAC's recommendations of better severity differentiation and relative value cost weights for

Medicare patients. Further, we acknowledge CMS' intent to implement MedPAC's recommendation and efforts, over the past year, in developing the HSRVcc weights and the CSA Grouper. However, we see CMS' proposed policy as a preliminary framework toward the goal of a significantly improved DRG payment methodology – A goal shared by CMS and the hospital community.

For the reasons we enumerate below, ***we urge that CMS not to implement the proposed cost weights or the severity grouper in FY 2007.***

"HSRVcc Weights"

The proposed weights will result in dramatic and harsh shifts in payments, both among providers (generally, from teaching/tertiary hospitals to community hospitals) and among cases (generally from surgical to medical cases). AHA estimates the magnitude of this shift is approximately $1.5 billion. The shift would be $9 million for our two major teaching / tertiary referral centers. First and foremost, any change in a methodology that results in such dramatic changes must be thoroughly vetted, tested and validated by all affected parties.

Such testing and validation is beyond the scope of individual hospitals and health care systems. Furthermore, a full vetting of these changes would require considerably more time than the 60 day comment period, and the necessary changes that would likely result would require considerably more time than is available before the final rule must be published. Fortunately, and to their credit, several hospital associations have, over the past 2 months, analyzed the data and information regarding the methodology available to them. We believe their results make an extremely strong case not to implement the proposed changes in the weights, both for FY 2007 and subsequently. Rather, we suggest, any implementation of cost-based weights should not occur until a robust methodology that clearly demonstrates significant improvement in payment policy has been developed. Strikingly, assessment of "payment accuracy" by two reputable bodies, The Moran Company and The Health Economics and Outcomes Research Institute (THEORI) found the CMS HSRVcc approach to be not at all or only marginally better than the current system.

Specifically, analysis performed on behalf of several hospital associations raised serious concerns regarding the HSRVcc methodology. As these concerns will be described in detail in the comments submitted by AHA and others, we will be brief. The analysis found a series of data errors, inconsistencies across databases and questionable methodological choices. One of these errors, the inadvertent inclusion of organ acquisition costs in the data

to set weights, significantly affected the impact of the proposed weight changes on our two academic medical centers. As noted above, it is beyond the ability of individual hospitals to uncover such errors or to determine whether complex adjustments such as trimming the data and weighting results are done correctly. The discovery of such errors or flaws in the methodology can only leave hospitals wondering whether there are other errors or flaws that will result in similarly large payment swings. Of a particular concern to us is the finding that these errors and flaws resulted in over-weighting of routine costs and under-weighting of ancillary costs. It was not a surprise to us that the most profound impact of this over / under weighting was on cardiology.

We further note that CMS made significant modifications to MedPAC's cost weight methodology. Instead of calculating costs at the claim level as MedPAC had done, CMS first calculated charge-based relative weights and then used national RCCs, aggregated into 10 cost centers, to convert these weights to cost-based weights. CMS argues, and we agree, that administrative feasibility is an important factor in choosing a methodology, particularly one that will require periodic updates. However, the shortcuts CMS is proposing to make this methodology more administratively feasible must be validated, particularly because such shortcuts could result in inadvertent cost dilution that affects certain categories of cases and hospitals.

Based on Partners' internal cost data of our two major teaching hospitals, the average margin of Medicare cases under DRGs with cardiac device costs is approximately breakeven under 2006 weights; however, the average margin drops to approximately –10% with the 2007 proposed HSRVcc weights. ***We investigated this phenomenon further and found that if we carve out costs associated with cardiac devices, the average margin returns back to breakeven.*** While we understand that this observation is based on only two hospitals in the nation, we believe that it raises a significant question about the HSRVcc methodology – Is the averaging process using a national CCR diluting the costs of high end cardiac devices to the extend that they are not reimbursed under the new weighting system; furthermore, if the dilution effect in the cardiac device cost center is proven true after evaluation, can CMS ascertain that similar cost compression does not occur in other cost centers, thus throwing the whole HSRVcc principle into question?

A fundamental assumption of the CMS methodology is that all revenue codes uniquely map to just one cost center, allowing a one-to-one match between the charge data on claims and the cost center specific CCRs. On the contrary, revenue codes are often "provided by" multiple cost centers. This overlap of claims and cost report data could result in distortions, and must therefore be carefully reviewed. One solution that may be required are more

specific cost report instructions so that hospitals' reporting of charge and cost data on the cost reports more closely matches the data on claims.

We therefore urge CMS to delay the proposed changes in the weights for at least one year and to work closely with the hospital industry and other interested parties to derive a robust methodology to derive cost-based weights. We agree with AHA that CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the results with sufficient time for hospitals and other interested parties to review and provide input and for CMS to respond to that input and make the appropriate modifications. We suggest that CMS immediately convene an Advisory Group of key stakeholders and experts, with meetings commencing in the fall.

Finally, should CMS choose to implement the HSRVcc weights in FY 2007, we urge that these weights be phased-in, at least over three years, to ameliorate the impact of the significant payment shifts, both across providers and across cases.

"Severity of Illness"

We support refinements in DRG classifications that better reflect patient severity and complexity. Such refinements can be done on a limited scale, such as the refinements CMS made to the cardiology DRGs last year, or on a large scale, as CMS is proposing for 2008. A large scale refinement will have significant ramifications for all affected parties, hospitals (particularly coding and IS staff), CMS, Fiscal Intermediaries and Vendors. Most would agree that the benefits of a large-scale refinement must be substantive and broad to justify the effort and costs involved. While we, again, commend CMS for its efforts to "put something on the table", we are concerned that the proposed CS-DRG methodology will not provide sufficient benefit for the entire industry to warrant the effort to adopt this new system. Furthermore, there are important questions (as described in the following paragraphs) associated with CS-DRG that must be addressed before it should be implemented.

Specifically, we question whether the APR-DRG system, in and of itself, is the best and most applicable severity system. According to AHA, CMS has not provided analysis that demonstrates that the proposed CS-DRG system improves hospital payment compared to either the existing DRG system or APR-DRGs. As CMS points out, the focus of the current DRG system is complexity while the APR-DRG system is on severity. We believe the complicated world of acute inpatient hospital care requires focus on both. While technological and conceptual constraints may well limit the ability of any DRG

classification system to encompass the best of both worlds, at the very least any new classification system should not have significant deficiencies. The inability of the proposed CS-DRG system to recognize technologies that represent increased complexity is, we believe, a significant deficiency. CMS makes dramatic revisions in the APR-DRGs to derive its consolidated system. A large part of this consolidation involves collapsing "tier four" cases – yet it is unclear whether these cases are sufficiently similar clinically and in resource use to justify such consolidation.

On a broader note, the APR-DRG system is based on the ICD-9 classification system. With ICD-10 on the horizon, does it not behoove CMS to seriously consider delaying this refinement until the next generation disease classification system is in place? Operationally, hospitals will need considerable time to purchase and prepare for a new classification system. The proprietary nature of the APR-DRG system and the resulting "hybrid" CS-DRG system, is of great concern to us. This, we believe, argues for CMS to strongly consider contracting with a vendor, perhaps 3M, to develop a "public domain" system. In particular, hospital coding staff will require training on any new classification system and the concomitant learning curve, while IS staff will need sufficient time to install the grouper and to ensure it properly "feeds" other data systems.

Finally, Fiscal Intermediaries will need to upgrade their systems to accept the full number of diagnosis and procedure codes required for any severity system to optimally classify patients. Providers currently submit 25 diagnosis and 25 procedure codes in accordance to the HIPAA compliance standards; however, most FIs only accept 9 diagnosis and 6 procedure codes. A study done by University HealthSystem Consortium found that, on average, the casemix using the full HIPAA standard dataset is 1.5% higher than that of the limited FI dataset. This suggests that the current system is not capable of facilitating the refinement that is the intended goal of the proposed change of classification system. Implementing the CSA-DRG before the system is ready to accept the data would undermine the tremendous amount of work that would be necessary to put forth in the system design. Furthermore, his would have downstream effects on the payment system: It would be virtually impossible to differentiate increases in casemix due to upcoding (if it occurs) from increases due to the correction of this system limitation.

Implementation of HSRV Weights and Severity of Illness

The two proposed refinements to the DRG payment system, addressing the DRG classification system and the relative weights for payment, should be inextricably linked:

- As we note above, it is doubtful that any DRG classification system can optimally address ***both*** severity and resource use. More likely, modifications will be necessary to correct the (hopefully) few anomalies that will exist. We believe it would be considerably more efficient and effective if the complete new system, i.e., classification and weights, was developed, vetted and validated at the same time.
- To some extent, and perhaps a large extent, payment changes arising from one aspect of the new system, say classification, will offset payment changes resulting from the other aspect, say weights. The proposed changes, for example, have demonstrated that, for teaching hospitals, reductions in payment under the cost weights would be partially offset by gains under a severity adjusted classification system. Such offsets would help the transition to the new system.
- It would be more efficient and effective for providers to implement the changes all at once.
- Finally, the change to the new system must be phased-in, at least for three years, to avoid large "cliff-like" payment reductions that would adversely affect some providers and potentially threaten access to care for beneficiaries. As CMS well knows, there is strong precedent throughout the history of its many prospective payment systems for phasing-in significant payment changes. Further, any such phase-in should be done in a simple, straightforward way. For example, phasing in a new grouper by simultaneously running two groupers (the old and the new) would create a significant administrative burden. CMS could, instead, establish transition corridors, phasing-in the level of gain and loss per hospital over the transition period.

CSA-DRG for IPF-PPS

One of the ongoing concerns of psychiatric providers is that the current DRG system does not provide adequate refinement within the Psychosis DRG 430. Based upon the 2004 MedPAR data grouped into CSA-DRGs, the current DRG 430 is further divided into 4 severity-of-illness levels and may address, to some degree, the current limitation with DRG 430. We ask CMS to clarify the agency's intent for implementing CSA-DRG system for other payment systems, such as the IPF.

"FTE Resident Count and Documentation"

We strongly urge CMS to rescind the so-called "clarification" in the proposed rule that excludes resident time spent in didactic activities in the calculation of payments for direct

medical education (when the activities occur in a nonhospital setting) and for IME payments (regardless of setting). The activities cited by CMS in the proposed rule, such as classroom lectures and seminars, are an integral component of the patient care activities engaged in by residents during their residency program. In fact, CMS' proposed position on didactic sessions is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as education seminars, classroom lectures ... and presentations of papers and research results to fellow residents, medical students, and faculty". These scholarly activities enhance residents' medical knowledge, directly benefiting the care of Medicare and all other patients, both those currently in the hospital and those to follow. To deny recognition of a medical knowledge activity "today" that will clearly benefit the care of a Medicare patient "tomorrow" is unfair.

In addition, CMS has failed to consider the significant administrative burden this proposal would impart on hospitals and Fiscal Intermediaries. Separating didactic time from patient care time will be very difficult, in some cases impossible, and would require significant revisions of rotation schedules and detailed accounting of the topics addressed in a lecture and the time for each topic. For example, a lecture often starts with a discussion of the care of a specific patient currently in the hospital – clearly included as patient care time under the proposed "clarification". It is likely that that discussion will then broaden to a discussion of the particular illness the patient has, including the results of research on that illness (excluded under the proposed "clarification") and then back to the specific patient (back to includable under the proposed clarification.). In the above example, when does the time stop being includable and then resume being includable? To carry the example further, the discussion of research results will enhance the resident's knowledge of that particular illness. The next week, a Medicare patient is admitted with the same illness – armed with that new knowledge, the resident asks the patient a question that would have been asked the next day, putting the patient at ease and expediting a treatment plan that gets the patient discharged a day or two earlier. Yet the time required to attain the knowledge that clearly benefited the care of that patient would be excluded for the purposes of IME under the proposed "clarification".

To be clear: Our opposition to this proposal is entirely based on the merits – we raise the administrative burden only to make CMS aware of this additional implication.

"Wage Data"

In the proposed rule, CMS addresses the instance where a new rural IPPS hospital opens in a State that has an imputed "rural floor" and proposes that the hospital would receive the imputed "rural floor" as its wage index until its first cost report is contemporaneous with the cost reporting period being used to develop a given fiscal year's wage index. This proposal is directly contrary to CMS treatment of the opposite situation, i.e., when a hospital "closes" its rural status, say, for example, by converting to a Critical Access Hospital. In the latter case, CMS has excluded the hospital from the calculation of the rural wage index based on the hospitals rural status in the **"rate year"**, despite the fact that the hospital's wage data is ***included*** in the wage data year used for that rate year. Under the proposed rule, CMS would ignore the hospital's status in the rate year when calculating the wage index, instead recognizing the hospital's rural status four years later when the cost report wage data "catches" up. We strongly oppose this inconsistent approach.

According to the AHA and others, the elimination of nearly 1,200 Critical Access Hospitals (CSH) has artificially increased the national average hourly wage leading to a significant underpayment to hospitals – AHA estimates the magnitude of this underpayment at $1.52 billion-dollar over five years (2003-2007). We ask that CMS carefully consider this issue.

"Geographic Reclassifications"

We ask CMS to carefully consider the comments made by the Boston Organization of Teaching Hospital Financial Officers (BOTHFO) and the Conference of Boston Teaching Hospitals (COBTH) requesting that CMS exclude the wage data for the Bristol County campuses of Southcoast Hospital Group, Inc., particularly in light of the recent reclassification of Southcoast Hospital to the Boston CBSA.

"Quality Data Reporting"

We recommend that the final rule delay the requirement for the reporting of the two SIP measures to qualify for the full payment update until the third quarter of CY 2006.

"Value Based Purchasing"

Partners' has a long-standing commitment to improving quality and efficiency for all patients in all settings. As such, we wholeheartedly support CMS in its efforts to improve the quality and efficiency of care delivered to Medicare beneficiaries.

Mark B. McClellan, MD, PhD, Administrator, CMS
Comments to Medicare Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY07 Rates, June 12, 2006

Overall, we commend CMS for its thoughtful approach in presenting in the FY 2007 proposed rule a framework to begin considering the many complex issues involved in developing a plan to implement value-based purchasing, as required by section 5001(b) of the DRA. Within this framework, CMS has put on the table many of the key issues and considerations and has asked the right questions. Yet, the considerable scope of such an effort, the many trade-offs that must be discussed and decided upon and the measured, thoughtful and comprehensive plan that hopefully will come as a result puts detailed comments in such a short time out of our reach. Rather, we strongly recommend that CMS seize the momentum started with this proposed rule and quickly convene a Value-Based Advisory Group to provide guidance and expertise to this effort. Partners HealthCare would participate. Through this Group, CMS could, for example, benefit from the experience and expertise of industry leaders in developing an infrastructure for reporting, collecting and validating data.

That said, we offer the following observations:

1. Validation of data by providers is critical – and worth the increase in the reporting lag. For example, there is a very effective data "feedback loop" between hospitals and the State agency that collects and reports quality data in Massachusetts. (In our opinion, the 9 month reporting lag cited by CMS is not problematic – in fact, we believe 6 months sets a very high bar)
2. For optimal performance, we believe the "bar" should be set high enough to serve as an effective target but not so high that it is attainable only by a small number of providers. We are worried that restricting differential higher pay to a very small percentage of facilities might only engage a small minority of facilities that feel such performance is attainable.
3. Balance the need for quality and efficiency measures that span all hospitals with the recognition that certain illnesses are only treated in specialized, tertiary care hospitals.
4. Balance the need to reap any savings achieved with the prudence to re-invest savings back into the system.
5. In our experience, having an EMR is the first step – and gaining maximal benefit requires effective use of the EMR. We think that more research is required in measuring effective use, including e-prescribing and use of structured problem lists.
6. The most effective and equitable bonus structure optimally blends performance achievement (i.e., hard target) with individual provider improvement. For illustration, we are attaching a graphic depiction of a performance / improvement quadrant model.

7. The data outflow from EMR is not currently uniformly structured across settings and products, making it difficult, and, in some cases, impossible to compare data from different systems. While the ideal will be to transition from administrative to clinical data, we understand that this will take considerable time, and CMS can play a positive role through incentives and insisting on common definitions and interoperable data fields.

Finally, we offer the following principles for quality data reporting

Accurate
- Clinical data should be preferred over administrative data if it is available

Clinically meaningful
- The measure actually matters to patients

Statistically rigorous
- Reporting includes indication of statistical reliability, and reporting at the most granular level that is statistically and functionally appropriate.

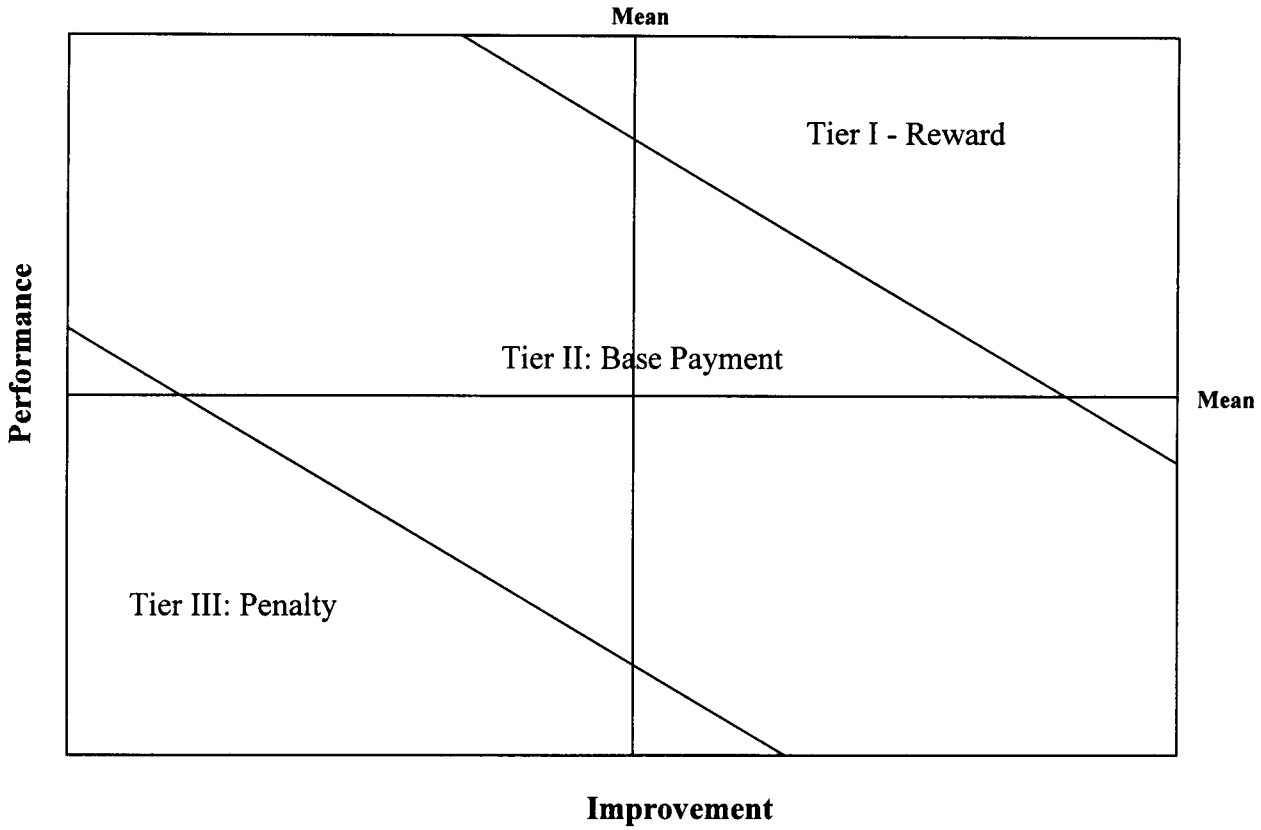
Risk adjusted
- Using best and most appropriate available risk adjustment tools

Transparent methodology
- Methodology and "rules" readily available to patients and to providers

Understandable to patients

Stable over time

Practical and expedient to obtain
- While we prefer clinical data, we recognize that administrative data sets are much less expensive to obtain and maintain



Tier I: Generally high performers – could include some average performers with very high level of improvement. Would allow exceptionally high performers to qualify even without improvement. At the highest level of performance, regression to the mean is more likely, and some high performers could be at a point of diminishing returns where continuing to exert efforts to improve in the area of focus would not yield large improvements.

Tier II: Generally average performers with average amounts of improvement

Tier III: Generally poor performers – even with a large amount of improvement, those with the worst performance would remain in the least favorable tier. At the lowest level of performance, progression to the mean can be mistaken for volitional improvement.

"Long-Term Care Hospital (LTCH) DRGs"

Unlike other Medicare prospective payment systems, LTC-DRG weight recalibration is not required to maintain budget neutrality. LTC weight recalibration resulted in an average casemix drop of 4.6% in the 2006 IPPS final rule and ***a further reduction of 1.4%*** in the 2007 IPPS proposed rule. Both MedPAC and CMS attributed the relative weight reduction to "lower charged cases being assigned to high weight DRGs"; however, neither provided further explanation on how lower charged cases were assigned to high weight DRGs.

Partners conjectures that the movement of lower charged cases into higher weighted DRGs is accomplished by improvement in coding; if so, the LTC-PPS, which is not constrained by budget neutrality, will self-correct this coding creep through this coding migration of lower charge cases into higher DRGs. **This non-budget neutral weight recalibration system will continue to correct for the casemix creep until coding improvement reaches a plateau, at which point, annual casemix variation will equal to the real casemix variation.** This phenomenon was first apparent to us in the weight recalibration of 2006, where using 2004 MedPAR data, the average casemix decreased by 4.6%, thereby correcting for the casemix creep of 2004. The same phenomenon occurs in 2007 weight recalibration, where using 2005 MedPAR data, the average casemix decreased by 1.4% correcting for the casemic creep of 2005.

In the 2007 LTC final rule, CMS stated the upcoding practice in 2004 as the justification for elimination of the 3.6% update. Given that we believe that 2004 casemix creep was already corrected through 2006 weight recalibration, we argue that the update elimination over-penalized LTC providers by a net of 4.2%:

A. 2007 LTC final rule CMS states that the 2004 casemix creep was	4%
B. 2006 weight recalibration resulted in a correction of	–4.6%
C. 2007 update elimination was	–3.6%
	-4.2%

Graph I, attached, shows a non-budget neutral weight recalibration system corrects for prior years' "artificial" casemix increases overtime. The Red Line depicts payment level if real casemix increase is 2.75%, as CMS' assumes in 2006 LTCH final rule. The Black Line depicts payment level of observed casemix increase (real casemix increase + casemix "creep"). The Black Line converges with the Red Line as casemix "creep" of initial PPS years cause casemix to drop in the out years. Finally, the Green Line depicts payment level where casemix "creep" correction through update is imposed on a non-budget neutral weight recalibration system.

We strongly urge CMS to recalibrate 2007 LTC-DRG weights in a budget neutral manner. For rate year 2008 and beyond, we urge CMS to work closely with National Association of Long Term Hospitals to establish a future update system that eliminates the possibility of over reduction due casemix creep by either:

A. Implementing a budget neutral weight recalibration system and address casemix creep through update, or
B. Maintaining the current non-budget neutral weight recalibration system but forgo any future update reduction for casemix creep.

Conclusion

We appreciate the opportunity to provide comments to the Proposed Rule for the Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. Please contact Anthony Santangelo, Corporate Manager, Government Revenue, by phone (617-726-5449) or email (asantangelo@partners.org) should you or your staff have any questions regarding these comments.

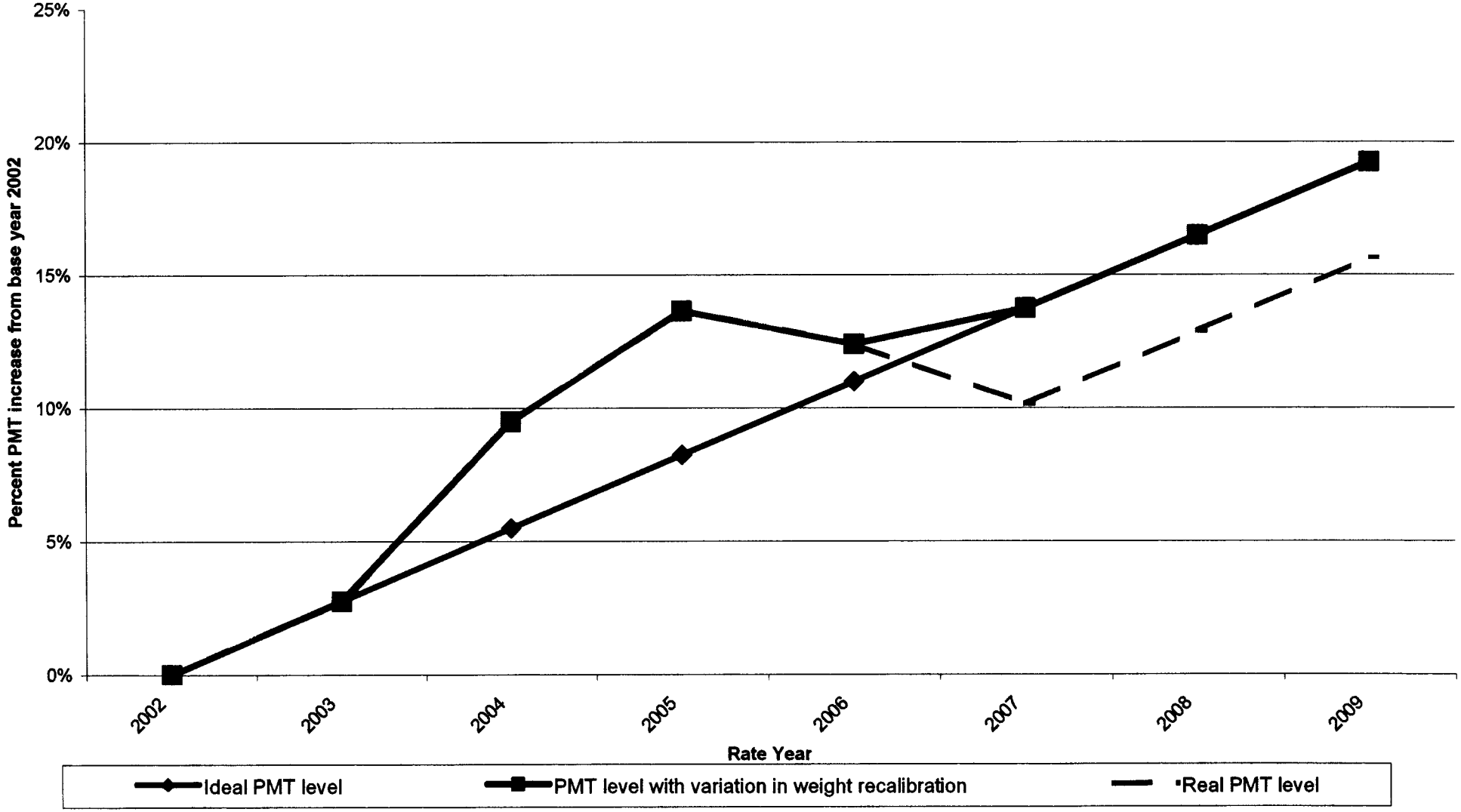
Sincerely,

Peter Markell

Peter Markell
Vice President for Finance

Mark B. McClellan, MD, PhD, Administrator, CMS
Comments to Medicare Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY07 Rates, June 12, 2006

Graph I: LTCH-PPS Payment Levels due to 1) real casemix increase; 2) observed casemix increase; and 3) observed casemix increase with elimination of update.



Mark B. McClellan, MD, PhD, Administrator, CMS
Comments to Medicare Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY07 Rates, June 12, 2006

Assumptions and Notes:

- Annual real casemix is 2.75%, per 3M study as stated in the 2007 LTCH-PPS final rule
- 2004 increase is 6.75%: 2.75% real + 4% coding. (Based on 2007 LTCH-PPS final rule.)
- 2005 increase is 4.15%: 2.75% real + 1.4% coding. (1.4% coding improvement is assumed to equal to 2007 proposed LTC-weight reduction based on 2005 MedPAR data.)
- 2006 increase is –1.25%: 2.75% real + -4% coding. (2006 final weights were based on 2004 MedPAR data, the reduction in weights were due to coding improvement)
- 2007 observed increase (Black Line) is 1.35%: 2.75% real + -1.4% coding. The system is at equilibrium with real casemix increases in the out years.
- 2007 real Medicare payment (Green Line): ***underpayment*** of 3.6% due to 2007 final LTC update elimination

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188
John Erwin
Executive Director

June 12, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

Attention: **CMS-1488—P**

Dear Administrator McClellan:

The Conference of Boston Teaching Hospitals welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006).

HSRV Weights/DRGS:Severity of Illness

In this proposed rule CMS has put forward potentially significant changes to the inpatient prospective payment system. Specifically, CMS has suggested a two step process of shifting from charge-based to cost-based DRG weights in FY 2007, to be followed by the implementation of severity based DRG weights in FY 2008.

We support efforts to further refine hospital payments under the PPS system, including adjustments intended to better capture severity of illness. However, changes of this magnitude could have considerable implications, in particular for teaching hospitals, which both treat the greatest number of highly complex cases and also utilize high volumes of ancillary services, classes of services that would both be affected by the proposed changes.

Developing "cost based" weights is a complex undertaking and there are numerous competing methodologies that have been offered for calculating the costs for a particular Medicare case. The methodology developed by the Medicare Payment Advisory Commission (MedPAC) is significantly different than the HSRV methodology included in CMS's proposed rule. In addition, there are modifications to both of these methodologies that should also be considered.

We believe more work is needed to determine the best way to develop cost-based weights, and therefore recommend that implementation of a "cost-based" DRG weighting methodology should be postponed for one year to allow for further work to identify an appropriate methodology.

We appreciate CMS's recognition of the need to better account for patient severity in Medicare payments. It is important that the DRG classification system reflect those cases that involve the sickest and most complex patients. We have concerns, however, about the proposed CS-DRGs, in part because they reflect patient severity only and do not recognize service complexity. CMS states that it plans to develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments. How CMS determines these criteria and their resultant impact on the classification system will have important implications for the IPPS.

To the extent that changes are offered intended to improve the payment system, they must be carefully analyzed and assessed. It is critical that the underlying policy rationale for the change be sound and implementation be accomplished with a methodology that best achieves the policy goal. For that reason, we believe additional analysis is needed before a significant change to the DRG weights can be implemented.

In summary, we recommend that the implementation of proposed changes with respect to a shift to cost-based charges and severity-weighted DRGs not occur on October 1, 2006, but rather should be postponed for one year. A one year delay would also allow for the simultaneous implementation of the new weighting methodology with refined DRGs. Each of these changes significantly redistribute payments, often in off-setting ways. Implementing both together would minimize the volatility associated with two separate changes.

Finally, because Medicare is a critical revenue source for hospitals, and because of the potential for significant disruptions in hospital operating revenues that could result, these reductions should be phased in over a reasonable period so that hospitals have time to transition to the new system without experiencing significant and relatively unexpected disruptions to operations. Historically, Medicare changes of significant magnitude have included some type of transition period. For example, the move to a PPS for capital was transitioned in over a 10 year period. Other changes that were accompanied by transitions include: implementation of the operating IPPS (four years), eliminating day outliers (four years), and removing the costs of teaching physicians and residents in the calculation of the wage index (four years).

"Resident Time in Patient Activities"

We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care" The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins].

We support the Agency's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

"Geographic Reclassifications"

The proposed rule contains provisions concerning the resolution of wage index issues involving a multicampus hospital with campuses located in more than one CBSA. We have followed with interest CMS' treatment of a case involving one such institution, Southcoast Hospital, which has three campuses – two in Bristol County, Massachusetts and one in Plymouth Counties in Massachusetts.

In 2004, Southcoast's decision to select Tobey Hospital in Plymouth as the Medicare provider number that would form the basis for its wage index designation (despite that fact that less than 10% of the hospital's total beds were located at this campus) resulted in the inclusion of Southcoast's entire wage base in the Boston wage area. Because at the time both Bristol and Plymouth counties were part of the Boston NECMA, the inclusion of the wages and hours of all three campuses in the Plymouth County campus did not affect the calculation of the Boston NECMA AWI.

However, with the reconfiguration of wage areas in 2005, Bristol County was assigned to the Providence CBSA and Plymouth County to the Boston CBSA. CMS continued to include the wages and hours of all three campuses in the Plymouth County campus, and therefore, the Boston CBSA, resulting in dramatically lower payments to the remaining hospitals in the Boston CBSA.

The Boston teaching hospitals have repeatedly urged CMS to take action to correct what we have viewed as a distortion of the intent of the wage index system and ensure accurate payment for the care delivered by hospitals in the Boston CBSA, as well as hospitals in surrounding counties that have reclassified into the Boston CBSA. In previous correspondence with CMS, the Boston Teaching Hospitals have urged CMS to correct the calculation of the Area Wage Index for the Boston-Quincy CBSA for IPPS Year 2007 by removing the wages associated with the Bristol County campuses of Southcoast Hospital from the Boston CBSA.

However, it has come to our attention that Bristol County hospitals have recently received approval from CMS to reclassifiy into Boston for the purposes of the wage index. Discharges

from Southcoast's Bristol campuses, as well as all discharges from the other three hospitals in Bristol county, will now get paid at the Boston reclassified AWI.

It is my understanding that under current statute, this decision by the Deputy Administrator would require that the wage data for Southcoast's Bristol County campuses be excluded from the calculation of the Boston CBSA area wage index. In the normal reclassification process, CMS adds the wages of the reclassifying hospital (in this case Southcoast and the other Bristol County hospitals) to the wages of the hospitals in the "core" area (e.g., Boston) and then calculates the AWI for all the hospitals together. If this "aggregate" AWI is more 1% or more lower than the original (pre-reclassification) AWI, the hospitals in the "core" area are held harmless.

Our analysis concludes that the inclusion of the Bristol County hospitals will reduce the wage index for the Boston CBSA by more than 1 percentage point. Therefore
for the purposes of the calculation of the area wage index, per Section 1886(d)(8)(C)(i) of the Act, the Secretary should calculate and apply the Boston CBSA wage index separately to hospitals located in the Boston CBSA, excluding Southcoast Hospital's Bristol Campuses and the other three members of the Bristol County Hospital Group.

In other words, hospitals currently within the Boston CBSA should continue to receive an AWI calculated and applied excluding Southcoast Hospital's Bristol campuses and the other reclassified hospitals. Southcoast Bristol campuses and the other reclassified hospitals would receive the aggregate AWI.

It is our hope that CMS will apply these precedents in the case of Bristol County's reclassification.

Thank you for the opportunity to comment on these issues. We look forward to continuing to work with CMS on these and other issues in the future.

Sincerely,

James Mandell MD

James Mandell, M.D., President and CEO
Children's Hospital Boston
Chairman, Conference of Boston Teaching Hospitals

LIFECARE
MANAGEMENT
SERVICES

June 12, 2006

By Hand

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1488-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule: LTC-DRGs

Dear Administrator McClellan:

On behalf of LifeCare Holdings, Inc. (LifeCare), which owns and operates long-term acute care hospitals, I am writing to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates" (the "Proposed Rule").[1] We appreciate this opportunity to comment on this important Proposed Rule, and look forward to working with CMS to ensure that this Rule is implemented in a manner that reflects our concerns.

I. INTRODUCTION

A. Company and Industry Background

LifeCare was founded in 1993. We currently operate 18 long-term care (LTC) hospitals, with 893 licensed beds in nine states. Our facilities employ approximately 2,800 people in various clinical and support capacities.

LTC hospitals provide services that are similar to that provided in short-term acute care hospitals, but must sustain these high levels of care for far longer periods. They also tend to treat more complex, severe cases than general acute care hospitals. Because of their high acuity patients, LTC hospital patients generally require more costly treatment resources than do general acute care hospital patients. As the Medicare Payment Advisory Commission (MedPAC) stated

[1] 71 Fed. Reg. 23,995 (Apr. 25, 2006).

in its March 2006 report, "LTCHs provide care to patients with clinically complex problems, such as multiple acute or chronic conditions, who need hospital-level care for relatively extended periods of time."[2]

LTC hospitals are able to provide these high levels of care because of their specialized experience and expertise in treating these more complex patients for extended periods of time. We provide patients with a multidisciplinary team approach to care that blends therapeutic interventions from diverse clinical disciplines. LTC hospitals have the specialized skill sets and competencies to treat those very ill patients who cannot respond adequately to typical short-term acute care hospital interventions. If LTC hospitals were not available to provide this level of care, these patients would be required to remain in general acute care hospitals, which are simply not equipped to provide high-level acute hospital care on a prolonged basis.

B. LTC Hospital Payment Background

Congress and the Secretary have long recognized that LTC hospitals have unique characteristics that require special payment status under the Medicare Program. LTC hospitals were formerly reimbursed on the basis of their reasonable costs, subject to the cost limits established under Section 223 of the Social Security Act Amendments of 1972.[3] In 1982, Congress passed the Tax Equity and Fiscal Responsibility Act,[4] which required the Secretary "to develop ... [M]edicare prospective reimbursement proposals for hospitals, skilled nursing facilities and to the extent feasible other providers."[5] In 1983, Congress mandated implementation of a PPS for most acute care hospitals, but specifically exempted LTC hospitals.[6] In enacting this provision, Congress expressly noted that "[t]he DRG system was developed for short-term acute care general hospitals and, as currently constructed, does not adequately take into account special circumstances of diagnoses requiring long stays."[7]

In response to growth in the number of hospitals excluded from PPS, in the Balanced Budget Refinement Act of 1999 (BBRA), Congress directed the Secretary to develop and implement for fiscal year (FY) 2003 a diagnostic related group (DRG)-based PPS for LTC hospitals that reflected the differences in patient resources and costs in these facilities.[8] This mandate was revised by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA),[9] which required the Secretary to "examine the feasibility and the

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[2] Report to Congress, Medicare Payment Advisory Commission (Mar. 2006) at 207.

[3] Pub. L. No. 92-603, § 223; 86 Stat. 1329 (1972).

[4] Pub. L. No. 97-248 (1982).

[5] Id. at § 101(a)(1).

[6] Pub.L. No. 98-21, § 601(a)(1) (excluding from PPS "a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days").

[7] H.R. Rep. No. 98-25. See also S. Rep. No. 98-23, at 54. ("The DRG classification system was developed for short-term acute care general hospitals and, as currently constructed, does not adequately take into account special circumstances of diagnoses requiring long stays and as used in the medicare program is inappropriate for certain classes of patients").

[8] Pub. L. No. 106-113 § 123 (1999).

[9] Pub. L. No. 106-554 § 307 (2000).

impact of basing payment under such a system on the use of existing (or refined) hospital diagnostic related groups that have been modified to account for different resource use of long-term care hospital patients as well as the use of the most recently available hospital discharge data."[10] In addition, BIPA noted that, if a different LTC hospital PPS could not be implemented by October 1, 2002, the Secretary should implement a LTC hospital PPS using the existing acute care hospital DRGs, modified where feasible to account for the resource use of LTC hospital patients.[11] BIPA also provides that the Secretary "*may* provide for appropriate adjustments to the long-term hospital payment system, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment ...."[12]

Pursuant to the BBRA and BIPA, therefore, the Secretary adopted a payment system for LTC hospital inpatient care based on prospectively set rates. The Final Rule adopting the LTC hospital PPS was promulgated on August 30, 2002.[13] The LTC hospital PPS utilizes the same DRGs as those used under the general inpatient PPS, with different weights to reflect the more intensive resource utilization in LTC hospitals. The annual update of the LTC-DRG classifications and relative weights is linked to the annual reclassification and recalibration of the inpatient PPS DRGs.[14] LTC hospitals are now in the fourth-year of a five-year transition to PPS from the reasonable cost payment system.

C. **Recent Payment Reductions**

LTC hospitals have been subjected to a number of significant Medicare payment reductions in recent years. Last year, in the hospital inpatient PPS Final Rule for FY 2006, CMS made substantial revisions to the weights for LTC-DRGs, resulting in an estimated 4.5 percent payment reduction.[15] In this year's LTC Hospital PPS Final Rule for rate year (RY) 2007, CMS adopted a zero percent market update, notwithstanding an anticipated 3.6 percent cost increase for LTC hospitals in RY 2007.[16] In this Final Rule, CMS also revised the payment methodology for short stay outliers (SSOs), defined as those stays that are shorter than 5/6 of the average length of stay for a LTC-DRG. Prior to RY 2007, payments for SSOs were made based on the lesser of: (1) 120 percent of the per diem amount for the specific LTC-DRG multiplied by the length of stay; (2) 120 percent of the estimated costs of the case; or (3) the full LTC hospital PPS payment.[17] The Final Rule added a fourth component to this formula, a blended rate of the per-diem payment amount under the inpatient PPS for short-term acute care hospitals and 120 percent of the LTC-DRG per diem payment amount.[18] Under this formula, as a patient's length

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[10] Id. § 307(b)(1).

[11] Id. § 307(b)(2).

[12] Id. at § 307(b)(1) (emphasis added).

[13] 67 Fed. Reg. 55,953 (Aug. 30, 2002).

[14] 71 Fed. Reg. at 24,049.

[15] *See* 70 Fed. Reg. 47,277 (Aug. 12, 2005).

[16] 71 Fed. Reg. 27,798, at 27,817 (May 12, 2006).

[17] 70 Fed. Reg. 4,647, at 4,685 (Jan. 27, 2006).

[18] 71 Fed. Reg. at 27,851.

of stay increases, there is a corresponding increase in the LTC-DRG component of the blended rate. These SSO changes are expected to result in a payment cut of 3.7 percent for LTC hospitals in RY 2007.[19]

CMS sought to change the SSO payment methodology in the LTC hospital PPS rule largely because it was concerned that LTC hospitals were "gaming" the system by inappropriately admitting patients in order to receive higher payments.[20] However, rather than reducing LTC hospital payments, MedPAC has recommended that the Secretary and Congress address this issue by defining LTC hospital eligibility criteria and patient admissions criteria so as to ensure appropriate admissions to these facilities.[21] MedPAC has also recommended that the Secretary require Quality Improvement Organizations to ensure LTC hospitals' compliance with any newly established hospital and patient criteria.[22] As you are aware, in response to MedPAC's report, CMS contracted with the Research Triangle Institute (RTI) to examine the feasibility of implementing MedPAC's recommendations. We understand that CMS anticipates RTI will submit its final report to the agency sometime this year.[23]

Now, in this inpatient PPS Proposed Rule, CMS is proposing, for the second time in two years, to reduce LTC hospital payments by re-weighting the LTC-DRGs. The proposed changes in this Rule will result in an estimated additional 1.4 percent payment reduction to LTC hospitals due to the proposed new LTC-DRG weights, which would be based on the most recent available – i.e., 2005 – MedPAR claims data. Cumulatively, these reductions amount to a cut in LTC hospitals' reimbursement of 13.2 percent, an unprecedented reduction in Medicare payments to any segment of providers.

II. THE PROPOSED RULE

A. The Cumulative Impact of the Proposed Re-Weighting and Other Recent Payment Reductions Threatens the Viability of LTC Hospitals

As described above, LTC hospitals in recent years have experienced substantial reductions in their Medicare payments. The 4.5 percent reduction adopted under the re-weighting for FY 2006, plus the 3.6 percent cut due to the market basket freeze for RY 2007, and then the 3.7 reduction under the revised SSO payment methodology for RY 2007, are already major retrenchments in LTC hospital reimbursement. CMS is now proposing an additional 1.4 percent cut. The cumulative effect of these reductions is simply not sustainable for our hospitals.

If the Proposed Rule is finalized, reimbursement to LTC hospitals will be reduced by approximately 13.2 percent over a two-year period. As a result, our hospitals will experience

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[19] The Proposed RY 2007 LTC Hospital Rule defined the fourth component as consisting entirely of the amount that would be payable under the general inpatient PPS, which would have resulted in a more substantial payment reduction of approximately 11.5 percent. 71 Fed. Reg. at 4,687.

[20] 71 Fed. Reg. at 4,685.

[21] *See* Report to Congress, MedPAC June 2004 at 130.

[22] Id. at 131.

[23] 71 Fed. Reg. at 27,885.

sharply lower Medicare margins. For the LTC hospital industry as a whole, Medicare margins would decrease in FY 2007 to -1.4 percent, from 3.4 percent in FY 2006.[24] This reduced level of funding for necessary Medicare patient care is unsustainable for those LTC hospitals such as LifeCare that concentrate on services that are heavily utilized by the disabled and elderly. Medicare patients comprise more than 80 percent of LifeCare's census.

As we commented at length in response to the RY 2007 LTC Hospital PPS Proposed Rule, to the extent that CMS continues to believe that patients are being inappropriately admitted to LTC hospitals, it should await the findings of the RTI study rather than using the blunt instrument of payment reductions to curtail these admissions. As we have stated to CMS on a number of occasions, the LTC hospital industry is eager to work closely with CMS to implement these findings. Until such time, CMS should not impose further reimbursement reductions on LTC hospitals.

B. The Secretary Should not Implement the Proposed Changes to the LTC-DRG Weights

In light of the devastating cumulative impact of these reductions, we request that CMS not implement the proposed additional 1.4 percent reduction in aggregate LTC hospital PPS payments through the proposed revised DRG weights for FY 2007. This is within CMS's discretion given its broad authority to establish the LTC hospital PPS rates under BIPA and the BBRA.[25]

Although these statutes contemplate that CMS shall use the most recently available hospital discharge data to establish the LTC-DRG weights, this requirement on its face applies only to the FY 2003 LTC-DRGs.[26] Indeed, this is the way that CMS has interpreted the parallel budget neutrality language in § 123 of the BBRA as applying only to FY 2003.[27]

These statutes, moreover, permit CMS to modify the DRG payment system as appropriate in order to account for the resource use of LTC hospital patients.[28] Notably, CMS has stressed its "broad authority" under the language of the above statutes in establishing the LTC hospital PPS.[29] As described below, the proposed aggregate 1.4 percent reduction in the LTC-DRG payments for FY 2007 would lead to less accurate, inadequate payments. Since CMS has broad open-ended authority to revise the weights appropriately to reflect current LTC hospital patient care, it should maintain the FY 2006 weights for FY 2007 to better account for the expected resources to be used by LTC hospital patients in FY 2007.

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[24] See Exhibit A.

[25] Pub. L. 106-113 § 123 (1999); Pub. L. 106-554 § 307 (2000).

[26] See Pub. L. 106-554 § 307(b)(2).

[27] See, e.g., 70 Fed. Reg. at 47,333. By regulation, CMS adjusted the standard federal rate for LTC hospitals for budget neutrality in FY 2003, but not for subsequent years.

[28] See Pub. L. 106-554 § 307 (the DRGs may be refined to account for differences in LTC hospital patient resource use and the LTC hospital payments may be adjusted by the Secretary as appropriate); Pub. L. 106-113 § 123 (the LTC hospital payment system is to reflect differences in patient resource use and costs).

[29] See, e.g., 70 Fed. Reg. at 47,334.

The differences in patient severity within the DRGs for LTC hospitals and general acute care inpatient PPS hospitals strongly support our recommendation to postpone the latest proposed LTC hospital payment cuts. It is well-accepted that the present LTC hospital PPS does not adequately account for differences in patient severity within the DRGs. Severity of illness within the DRGs is a greater issue for the LTC hospital PPS than the general acute care hospital inpatient PPS. For example, more than twice as many LTC hospital patients are high-acuity patients as compared to inpatient PPS patients. 52 percent of all LTC hospital patients are in the highest "Risk of Mortality" categories compared to only 24 percent of general acute care hospital patients.[30] Similarly, 69 percent of LTC hospital patients are in the highest "Severity of Illness" APR-DRG categories, as compared to 33 percent of general acute care patients.[31] LTC hospital Medicare patients also have multiple comorbidities, are less stable upon admission, and more likely to be disabled, than other post-acute care patients.[32]

Although such differences in severity of illness within the DRGs are, therefore, an important factor for LTC hospitals, CMS decided in 2002 not to adopt severity adjustments to the LTC-DRGs.[33] The agency decided not to do so in order to permit more time for study of severity issues and to resolve whether to implement severity adjustments to the inpatient PPS-DRGs.[34]

Significantly, CMS has studied the severity issue extensively since 2002. The agency now plans to adopt severity-adjusted DRGs for inpatient PPS, probably for FY 2008, in order to improve the accuracy of the DRGs. CMS further states that severity-adjusted LTC-DRGs will be considered for FY 2008 in tandem with the inpatient PPS severity-adjustment changes. Severity-adjusted DRGs are expected by CMS to better account for differences in severity of illness and the associated costs across hospitals.[35]

Nonetheless, CMS proposes a 1.4 percent reduction in aggregate LTC hospital PPS payments under the proposed revised LTC-DRG weights for FY 2007.[36] As explained by the agency, this reduction is substantially caused by more relatively lower charge cases being assigned to the LTC-DRGs with higher relative weights due to hospital improvements in coding since 2002.[37] This expected net reduction in the LTC hospital payment rates under the proposed FY 2007 LTC-DRG weights is therefore substantially attributable to more less severe cases being assigned to relatively high resource use DRG classifications in the FY 2005 MedPAR data.

Based upon the foregoing, substantial revisions to the Medicare prospective payment systems to adopt severity-adjusted DRGs for FY 2008 are likely. If this proceeds as planned, the LTC-DRGs are expected to become much more accurate in matching payment levels to the different cost resources required by the various types of patients across LTC hospitals. In light of these important pending DRG changes, CMS should postpone the latest proposed LTC hospital

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[30] Source: 2004 MedPAR data.

[31] Source: 2004 MedPAR data.

[32] See 67 Fed. Reg. at 55,965.

[33] See id. at 55,966.

[34] Id. at 55,967.

[35] See 71 Fed. Reg. at 24,051, and 24,025.

[36] See 71 Fed. Reg. at 24,413.

[37] Id.

payment reductions for FY 2007 based on revised LTC-DRG weights until FY 2008. Otherwise, the payment rates for the more typical resource-intensive LTC hospital patients will be diluted by the FY 2005 upcoding of many lower severity cases to the higher weight DRGs.

This is critical to accurate rates because the new, already adopted SSO policy is intended by CMS to reduce future LTC hospital admissions of short-stay patients.[38] Assuming that fewer of these less severe cases will be treated in LTC hospitals in FY 2007, the increased average severity of the remaining patients should be reflected in the rates. Instead of addressing coding improvements and severity patterns piecemeal through reductions to the FY 2007 LTC-DRG weights that ignore the need for corresponding adjustments to reflect the greater cost of relatively more severe LTC hospital cases, for whom LTC hospital care is most warranted, CMS should address coding improvements comprehensively for FY 2008 in the context of the improved severity measures to be adopted.

The ongoing LTC hospital PPS transition period from the reasonable cost payment system, as reflected in the FY 2005 MedPAR data, also supports this request to postpone further LTC-DRG weight adjustments until FY 2008. As CMS points out, the 2005 MedPAR claims data were "still in flux" because LTC hospitals were then in the midst of the transition period from the former reasonable cost payment system.[39] During the transition period, only a portion of the payment for each case is based on the LTC hospital PPS. Many claims in this database still lacked sufficient information to accurately code the claims.[40] Since these transition-period data are still not fully accurate for LTC hospital PPS, this is another reason for CMS to postpone further LTC-DRG rate reductions until better data more fully reflecting the LTC hospital PPS payment system are available.

III. **Conclusion**

We appreciate the opportunity to comment on the important issues raised by the Proposed Rule and urge you to address our concerns in a manner that fully protects Medicare patient access to medically necessary LTC hospital treatments for complex conditions. We request that CMS carefully consider the recommendations offered above in determining appropriate reimbursement levels for LTC hospitals. Please contact me if we can provide you with any additional information or assistance.

Sincerely,

Jill Force
Executive Vice-President
LifeCare Holdings, Inc.

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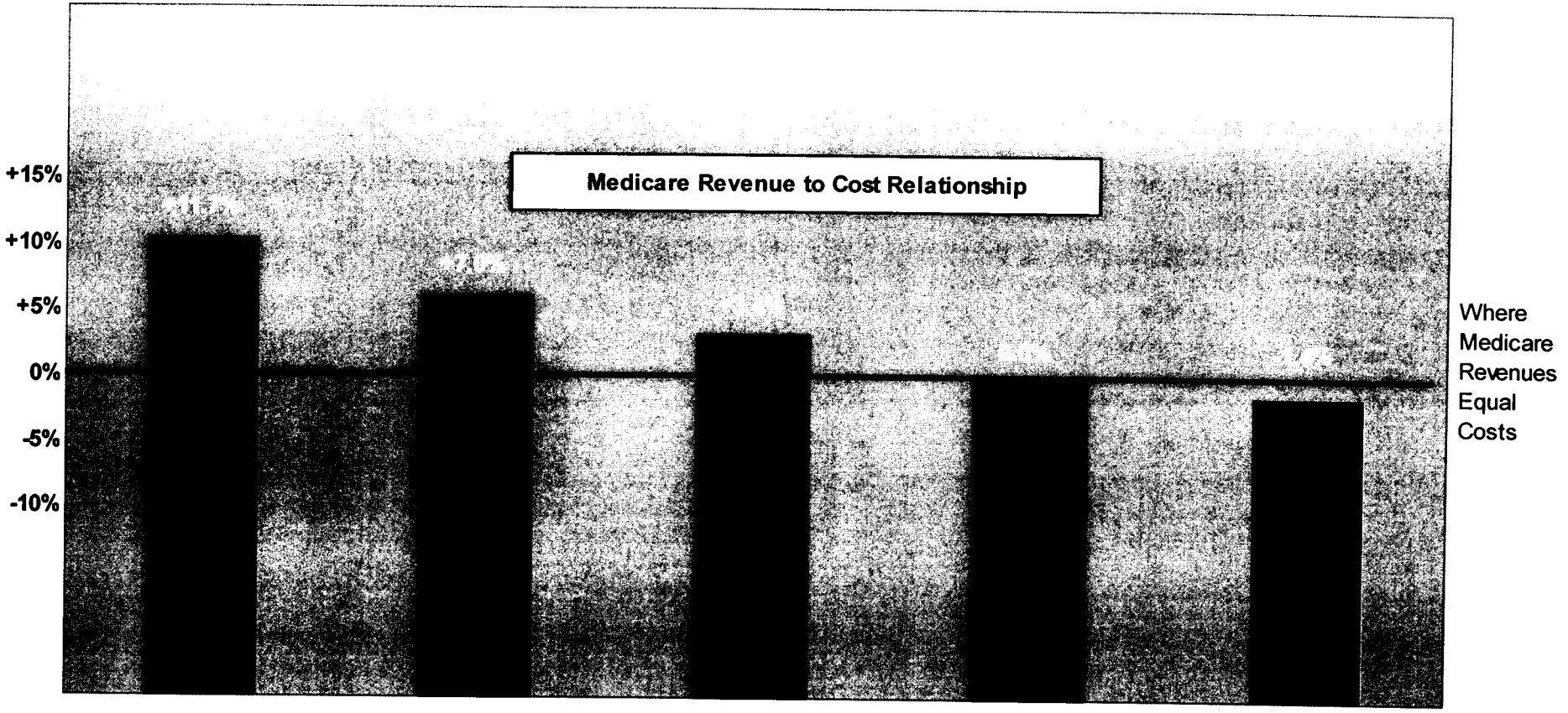
[38] See 71 Fed. Reg. at 27,895.

[39] See 71 Fed. Reg. at 24,413.

[40] Id. at 24,059.

Exhibit A

CMS Proposes Rates Below the Costs of Caring for the Medically Complex LTCH Population



2004:
CMS estimates LTCH Medicare revenues exceeded costs by 11.7%.

October 1, 2005*:
CMS lowers LTC-DRG weights, reducing payments by 4.5%**

May 2006*:
CMS estimates LTCH cost increases of 3.6% but provides a zero percent market basket update

May 2006*:
CMS LTCH PPS Final Rule for RY 2007 reduces payments by 3.7% under revised SSO methodology

April 2006:
CMS's proposed inpatient rule for FY 2007 would re-weight LTC-DRGs, resulting in an additional 1.4% payment reduction

*** Estimates – assumes no changes in volume or intensity of services, which could affect total costs**

**** Note: CMS rebases LTC-DRG weights annually, with an effective date of Oct. 1 of each rate year. This rebasing is not budget neutral.**

AstraZeneca

190

Stephen D. McMillan
Director Government Reimbursement
Federal Government Affairs

Tel 202 350 5577
Fax 202 350 5510

June 12, 2006

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, 71 Fed. Reg. 79, 23996 (April 25, 2006) [File Code: CMS-1500-P]

1488

Dear Dr. McClellan:

AstraZeneca (comprised of AstraZeneca Pharmaceuticals LP and AstraZeneca LP) is pleased to submit comments on the proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) to implement Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year (FY) 2007 Rates (the Proposed Rule), 71 Fed. Reg. 23,996 (Apr. 25, 2006). We appreciate this opportunity to share our views on the important changes proposed to the overall diagnosis-related group (DRG) structure, as well as on their impact on payment for stroke cases.

AstraZeneca is one of the world's leading pharmaceutical companies, engaged in the research and development of new medicines that can allow Medicare beneficiaries to lead longer, healthier, and more productive lives. In keeping with this commitment, AstraZeneca has a long-standing drug development program targeted at effective therapies for stroke. In the course of working with the stroke community, AstraZeneca has observed wide variation in stroke severity, and has conducted research demonstrating the systematic under-reimbursement of hospitals for the services they deliver to stroke patients.[1] AstraZeneca therefore applauds CMS's consideration of the 2005 Medicare Payment Advisory Commission (MedPAC) recommendations to refine the current DRG system to better recognize severity of illness and more accurately reflect the actual costs of care delivered for different disorders, including stroke. In addition, AstraZeneca agrees that there is a need to develop criteria for distinguishing between care complexities within CMS's proposed consolidated severity-adjusted DRGs.

The following comments address a number of specific considerations raised by the suggested changes in the Proposed Rule. We are available to provide additional information about any of these items or answer any questions you may have.

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[1] Marotta C, Scharf J, Mafilios M, et al. Impact of length of stay and costs on the ability of hospitals to adopt new technology for the treatment of acute ischemic stroke patients [poster]. Presented at: ASA International Stroke Conference; February 15-17, 2006; Orlando, FL.

HSRV Weights

Support for Cost-Basis of DRG Weighting

AstraZeneca supports CMS's decision to implement the recommendation made by MedPAC in 2005 to move from a charge-based DRG relative weight methodology to one that is based more closely on the actual cost of providing care. We agree that concentration of surgical cases in high-cost hospitals, and differential markups for goods and services provided by hospitals, have distorted DRG weights and payments under the current methodology.[2] As stated above, our own analysis has indicated that hospitals are systematically under-reimbursed for providing stroke care to Medicare beneficiaries. Consequently, we are pleased to note that in Table I of the proposed rule, CMS has estimated that the hospital-specific relative value cost center (HSRVcc) methodology will have a positive 3.2% payment impact on DRG 14 for intracranial hemorrhage and cerebral infarction.[3] Even a modest payment improvement such as this would somewhat increase beneficiary access to high-quality stroke care, including new technologies for stroke treatment. Nevertheless, despite this positive change, AstraZeneca acknowledges stakeholder concerns about the precision and accuracy of both the proposed HSRVcc methodology and CMS's calculations, and respectfully urges CMS to focus on and address these concerns prior to the implementation of this methodology. In the event that CMS cannot address these concerns to the satisfaction of the stakeholders in time for the FY 2007 final rule, then AstraZeneca recommends a delay of implementation of the HSRVcc methodology until FY 2008 so that these concerns can be addressed.

DRGs: Severity of Illness

Limitations of Consolidated Severity-Adjusted DRG System

AstraZeneca also commends CMS's proposed action on the 2005 MedPAC recommendation to refine the current DRGs to better recognize severity of illness. We agree with CMS's intent in its proposal to adopt a severity-adjusted DRG system that provides a more granular breakout of DRG assignment and increases the precision of inpatient case description. However, AstraZeneca believes that CMS's consolidated severity-adjusted DRG system, as proposed, does not adequately account for various levels of case severity that may exist within a given principal diagnosis or base DRG, even in the absence of complications and co-morbidities. Specifically, we believe that CMS's methodology incompletely distinguishes among severity levels in stroke cases, where the severity of the stroke itself can be independent of co-morbidities.

Therefore, AstraZeneca respectfully urges CMS to further refine its proposed consolidated severity-adjusted DRG system to reflect the potential for increased case severity independent of co-morbidities. We would be pleased to work with CMS to develop a solution that resolves this problem for the stroke and other DRGs. Such a refinement would not only increase the precision of DRG assignment, but it would also better account for average cost differences between cases that are not separable on the basis of complications and comorbidities. To allow time to accomplish this refinement, we support CMS's proposal to delay implementation of the consolidated severity-adjusted DRG system until FY 2008.

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[2] 71 Fed Reg. at 24,021.

[3] Id. at 24,023.

Criteria Used to Recognize Increased Complexity in the Consolidated-Severity Adjusted DRG System

AstraZeneca agrees with CMS that there is a need to "develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments."[4] As CMS notes, the structure of the APR/consolidated severity-adjusted DRG system does not currently accommodate distinctions based primarily on complexity of care, which often are independent of disease severity. Because the complexity of care directly affects case costs, the proposed system's inability to recognize these factors risks under-reimbursing hospitals for cases involving complex technology and, therefore, limiting beneficiaries' access to that technology.

An example of complexity recognized in the current DRG system that would be lost in CMS's proposed system is DRG 559 – *Acute ischemic stroke with use of thrombolytic agent.* This DRG was created for FY 2006 to account for the fact that a separately identifiable technology was being used in stroke treatment that significantly increased the case cost above the mean for untreated stroke cases. We note that in CMS's proposed consolidated severity-adjusted DRG system, there appears to be no similar DRG, and conclude that these cases have been folded back in to the proposed severity-adjusted DRGs 56 – 58. This proposed regrouping appears to disregard the complexity inherent in the use of a thrombolytic agent. Consequently, to ensure continued beneficiary access to appropriate diagnostic and therapeutic technologies for stroke and other diseases under the IPPS, AstraZeneca recommends that CMS refine the proposed consolidated severity-adjusted DRG system to account for differences in case complexity, including the difference in complexity created by the use of a thrombolytic in stroke.

We note that the relative brevity of the comment period does not permit the in-depth analysis needed to fully validate any proposed solution to the complexity problem identified by CMS. Notwithstanding that limitation, we believe that there still is value in proposing criteria and a process that have the potential to successfully address this problem. We have made such a proposal below.

Specifically, we recommend that therapeutic complexity be accounted for in DRG assignment when it is the consequence of a separately identifiable technology that provides a clinical benefit for Medicare beneficiaries and results in significantly higher case costs independent of severity level, relative to the base DRG. These criteria are conceptually very similar to those of the existing new technology add-on payment. However, because both old and new technologies can increase case complexity, "newness" is not a criterion that we recommend. We further recommend that complexity levels be superimposed on the proposed severity of illness levels, such that either severity or complexity, or a combination of the two, would increase the classification of a case. These classifications would be defined as "Severity of Illness or Complexity (1-4)".

We further propose that complexity-increasing technologies be identified by the ICD-9 code of the associated procedure. We recommend that CMS develop and maintain the list of qualifying procedures through rulemaking, to allow for a public and transparent process. We believe that it should be feasible for CMS to do so using the following four-step algorithm.

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[4] Id. at 24,014

1. CMS would identify and eliminate simple or minor procedures. Such procedures should not materially impact the resource intensity of a case.

2. CMS next would identify and eliminate procedures that direct severity-adjusted base DRG assignment and therefore are explicitly reflected in their base DRG's relative weight. Such procedures must appear in a specific base DRG, and therefore cannot increase case complexity relative to that DRG.

3. CMS then would identify and eliminate procedures that, while not directing DRG assignment, are nevertheless standard of care for most cases with a particular diagnosis. Such standard-of-care procedures would have a resource impact already fully reflected in the relative weight(s) of the base DRG(s) in which they appear, and therefore would not increase complexity relative to these DRGs.

4. The remaining group of procedures would comprise those that are non-trivial, do not direct DRG assignment, and are not standard of care for most cases with a particular diagnosis. Though it is reasonable to conclude that most of these would increase case complexity, it is possible that not all would cause mean case resource intensity to deviate significantly from that of the relevant base DRG(s). Therefore, as the final step CMS would identify and test all cases involving each such procedure, grouped by base DRG, against a base-DRG-specific cost or charge threshold determined for all cases without regard to severity. This threshold could be similar to that used to determine new technology add-on eligibility. If the mean charge or cost for a procedure-specific group of tested cases exceeded the threshold, then the procedure would be considered complexity-increasing for that base DRG. A weighted mean test across all of the relevant DRGs for the procedure should not be applied, as we believe that complexity should be specific to an individual base DRG.

We recognize that assessing clinical benefit for the complexity-increasing procedures may be problematic, but we also understand CMS's need to avoid providing higher complexity-based payments for cases that use a clinically inappropriate procedure. However, we anticipate that the number of needed clinical assessments will be small, as a relatively small number of procedures should pass through the algorithm described above.

Finally, we propose that each billed case be tested individually for assignment to a complexity-based level, since the use of a complexity-increasing procedure would not necessarily increase a specific case's resource intensity. We illustrate our proposed case-specific testing process with the stroke-related example below.

Because CMS previously recognized the complexity-increasing nature of thrombolysis in ischemic stroke by creating DRG 559, we expect that (using our proposed algorithm) the procedure for administering a thrombolytic would be judged a complexity-increasing procedure for DRGs 56 – 58.

We propose that an ischemic stroke case in which a thrombolytic agent was used would first be grouped to the appropriate severity/complexity level on the basis of comorbidities. Then the specific case costs or charges would be compared with the mean costs, charges, or payment for that severity/complexity level. If the specific case exceeded the mean(s) or the payment for that level by a

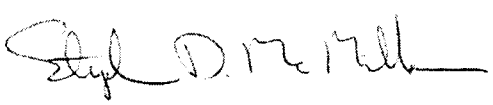
certain amount or percentage, the case would be moved upward one level and the case retested, continuing iteratively until the case moved to the highest severity/complexity level or the case cost or charges failed to pass the test. Please note that we have not proposed a specific test (i.e., costs, charges, or payment) and threshold or difference for grouping individual high-complexity cases to the appropriate higher severity/complexity level. We believe that this can only be done following a full analysis of charges, costs, and payments for all of the proposed severity-adjusted DRGs, so that a broadly applicable test and threshold can be developed. AstraZeneca would be pleased to work with CMS to facilitate such an analysis and develop the test and threshold.

AstraZeneca strongly believes that adopting this proposal could solve the complexity dilemma that CMS has identified, and also that it should be compatible with the new technology add-on payment process. Nevertheless, we respectfully urge CMS to ensure that as it recognizes complexity in the proposed system of severity-adjusted DRGs, it preserves the intent and substantive benefits of the new technology add-on payment, so that beneficiaries do not experience reduced access to important new inpatient technologies.

* * * * *

Again, AstraZeneca appreciates the opportunity to comment on the Proposed Rule. We look forward to continuing our work with CMS to promote high-quality stroke care for Medicare beneficiaries. Please do not hesitate to contact me at (202) 350-5577 or by electronic mail at Stephen.S.D.McMillan@AstraZeneca.com if you have any questions or need further information about these comments.

Sincerely,



Stephen D. McMillan
Director, Government Reimbursement

Cc: Marc Hartstein

191

National Association of
Children's Hospitals
and Related Institutions

NACHRI June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1488-P, Medicare Program, Proposed Changes to Hospital IPPS

Dear Dr. McClellan,

This letter is to provide the comments of the National Association of Children's Hospitals & Related Institutions (NACHRI) to CMS on the 4/25/06 Medicare program proposed rule, Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, 42 CFR Parts 409, 410 et al (file code CMS-1488-P).

The NACHRI comments presented in this letter focus on three main areas:

(1) the proposed refinement of costing and statistical methods for calculating DRG relative weights ("HSRV weights");

(2) the proposed refinement of DRGs based on severity of illness ("DRGs: Severity of Illness");

(3) the proposed recalibration of relative weights, specifically for low case volume DRGs ("DRG weights").

Please note, these NACHRI comments are separate and in addition to the comments submitted by the National Association of Children's Hospitals (N.A.C.H.) which focus on issues involving "grandfathered hospitals-within-hospitals."

Children's hospitals treat only a small number of Medicare patients but this proposed rule is of great significance for a number of reasons. This proposed change is very important for the Medicare IPPS itself, for other federal and state programs that follow Medicare methodologies, and for the rest of the hospital industry which often follows

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the precedents set by Medicare. Of particular importance to children's hospitals is the federal Children's Hospitals Graduate Medical Education funding program, administered by HRSA, which is designed by statute to follow as closely as practical the Medicare IPPS methodology for payment to hospitals for graduate medical education costs and indirect medical education costs.

The proposed changes of this proposed rule -- the movement from charge based weights to cost based weights and the movement to severity adjusted DRGs, represent the most significant changes to the basic methodologies of the Medicare IPPS since its inception in 1983. We think these are important initiatives and believe it is important to undertake such initiatives to improve the accuracy, equity and incentives in the Medicare IPPS. At the same time, we have many questions and concerns about the specific proposals. We believe it is essential to address all the specifics for each major initiative as well as the combined effects of all contemplated changes before implementing changes on the scale of what is proposed. We offer a number of specific recommendations in this letter and would welcome the opportunity to provide further information and assistance.

II (C) (2) Proposed Changes to DRG Classifications and Relative Weights: Refinement of IPPS Relative Weight Calculation ("HSRV Weights")

Overview: NACHRI is supportive of the intent of the CMS proposal to move from charge based weights to cost based weights, but we have a number of questions and concerns and recommendations for change for the proposed new HSRVcc methodology which we believe need to first be addressed. We also believe it is important for CMS to be explicit about recognizing the limitations of its proposed costing methodology and its applicability to non-Medicare patients as this is a major precedent setting change for the entire hospital field.

We agree that the use of charge based weights overstates the cost of care for many procedure based DRGs where there are higher markups of charges over costs, and understates the cost of care for DRGs where a larger proportion of care is for room & board and nursing services where there are lesser markups of charges over costs. In separate analyses, we have found this to be an even greater problem for pediatric patients since a larger proportion of their care is for room & board and nursing services and a lesser proportion is for ancillary services.

In our studies, we have found an additional bias to the use of departmental cost to charge ratios (CCRs) is that the unit costs are higher for providing many services to children, especially young children and services that are labor intensive such as nursing and respiratory therapy, but this is not reflected in the department-wide CCRs. The proposed HSRVcc methodology does not provide a framework for addressing these additional issues. Ideally it would, but if it is not possible for the Medicare program to address these issues, at a minimum we *request* that the CMS

final rule recognize these additional costing issues and their implications for the applicability of the Medicare HSRVcc methodology for non-Medicare patient populations. (Note, we make a similar request in the next section of our comments regarding the proposed CS-DRGs and their applicability to non-Medicare patient populations.)

We have a number of questions and concerns about the specifics of the proposed Hospital Specific Relative Value cost center (HSRVcc) methodology, its strengths and weaknesses, and its impact on the accuracy of costing for various patient subgroups, not just those highlighted in the proposed rule for medical versus surgical patients and cardiac procedure and orthopedic procedure patients. Following are our comments on the overall merits of the CMS proposed methods compared to MedPAC methods and other methods, and then our specific questions, comments and recommendations for each of the six steps of the CMS proposed HSRVcc methodology.

Overall Merits of CMS versus MedPAC versus Other Costing Methodologies: The CMS proposal rule cites two advantages to the CMS methodology - - that it avoids the complexity of dealing with hospital-specific cost center CCRs and that it enables more current claims data to be used. CMS also indicates it believes its approach would achieve similar results to that of MedPAC but does not provide any information about this. Because the selection of HSRV methodology is so very important, we *request* that the proposed rule provide specific information on how the results differ between the CMS methodology and the MedPAC methodology and the accuracy with which each methodology links payment to cost.

Step One: Clean the Data. Perhaps it has been explained in a previous year's NPRM, but since this year's proposed rule represents such a major revamping of the Medicare IPPS methodology, it is *requested* that CMS explain again the purpose and impact of its approach to removing statistical outliers and clarify its specific definitions.

Here are several more specific questions. Is it the intent to remove as statistical outliers just those cases whose values are so extreme as to be questionable data or is it the purpose to remove a broader set of extreme patients whose inclusion may unduly skew the relative weights? Does the current criteria require a patient's charges to exceed 3 standard deviations for both charges per case and charges per day or just one of these two criteria? How many cases are removed as outliers for these different criteria? Is this sufficient to achieve the intended purpose?

We note that the approach to statistical outliers is important to the stability of relative weights overall, and in particular, to the low volume DRGs. We comment further on this in our later comments for section II (E), Proposed Recalibration of DRG Weights, which deals with efforts to produce more stable weights for very low volume DRGs (mostly DRGs for 0-17 year olds).

Step Two: Compute HSRVs for Each Cost Center for Each DRG. There are two important issues here. The first is the selection of cost centers. There are 10 cost centers selected and these are displayed in Table A, but there is no explanation given as to why the various different cost centers were consolidated as they were into these 10 cost centers. We *request* that CMS explain its rationale for consolidating to these 10 cost centers, and specifically, present information and analyses as to whether these consolidations cause certain services to be under-costed or over-costed. For example, it would seem that the cost to charge ratios (CCRs) for medical/surgical supplies might be different than durable medical equipment but these were combined yielding the third largest cost center.

The second issue is that it is very difficult to read and understand the methodology described for computing HSRVs for each cost center for each DRG. It is thus very difficult to assess and offer comments. We *request* that this be rewritten in a more explicit and exacting step-by-step manner. It might be best if the many steps could be numbered and put in a table format with terms and expressions consistently used.

Step Three: Compute CCRs From the Cost Reports for Each of the 10 Cost Center Groups Identified in Table A. There are two very important issues here. First, the data editing thresholds seem much too loose. It is hard to conceive of a departmental CCR greater than 10 (i.e., costs ten times higher than charges) or less than .01 (i.e., costs less than 1/100 of charges) being correct and valid. We *recommend* that tighter editing standards be developed and that the rationale and impact of the editing thresholds be explained.

The second issue is the method used to calculate the CCR mean values. We believe the method used is fundamentally flawed and produces distorted values. There are two problems here. First, nationwide average CCR for each of the 10 cost centers is calculated by averaging the CCRs from all hospitals (i.e., averaging the averages), rather than summing all the costs and all the charges for each cost center from all hospitals and dividing the total costs into the total charges. The proposed rule, by averaging all the averages, allows the smallest hospital to have the same impact as the largest hospital on the calculation of the nationwide average CCRs. This is inappropriate and wrong.

The second problem is that the proposed rule limits the impact of relatively more extreme values by removing all hospital CCR values beyond 2 standard deviations (95^{th} percentile) and by calculating the CCR as a geometric mean rather than an arithmetic mean. These are all CCR values that have passed edit screens but nonetheless are removed.

These methods produce distorted results. The current charge based weights appear to somewhat underpay for medical DRGs, but the proposed new method would appear to reverse this problem and overpay for medical DRGs. This occurs because the proposed methods produce CCRs that are considerably higher than they should be for

certain cost centers which comprise a greater proportion of the care for medical DRGs. Specifically, while the markup of charges over costs are generally a lot less for room & board/nursing services than ancillary services, the proposed rule produces exaggerated values --- CCRs of .85 and .72 for routine days and intensive care days, which are much higher than the values of .66 and .54 calculated when total costs are simply divided into total charges for each cost center.

We *recommend* that once more rigorous data editing screens are applied, that the CCRs be calculated by dividing all of the costs into all of the charges for each cost center to produce an arithmetic mean value for each CCR.

Step Four: Sum the Average Charge for Each Cost Center From the MedPAR Data and Apply the National CCRs From the MedPAR File. This is the step to identify the proportion of all costs attributable to each cost center, referred to as the "scaling" factor. One illustration is provided, that of routine costs representing 29% of all costs (when a CCR of .85 is applied). It is important that all the scaling factors be presented. We *recommend* that the scaling factors be presented in a table and be shown for all 10 cost centers for all patients and then separately for medical and surgical patients.

Step Five: Adjust Relative Weights From Step Two to Cost by Applying Scaling Factors from Step Four. In order to understand how the HSRVcc methodology is actually working, we *recommend* that a table be included that shows for each DRG the proportion of charges attributable to each cost center and the relative weight for each cost center after the scaling factor is applied along with the total relative weight for each DRG.

Step Six: Normalize the Weights. We have no comments on this step.

II (C) (3) Proposals for Revisions to the DRG System Used Under the IPPS: Refinement of DRGs Based on Severity of Illness ("DRGs: Severity of Illness")

NACHRI believes it is very important for the Medicare DRG system to continue to update the classification system component of its IPPS to reflect the state of the art methods for categorizing and distinguishing severity levels for hospitalized patients. NACHRI has the following comments and recommendations for the Consolidated Severity Adjusted DRGs (CS-DRGs) that CMS has proposed.

(1) Severity Adjusted DRGs: We believe it is best, if possible, to work towards a consistent and comprehensive approach to severity adjusted DRGs. If this is done thoroughly, it should increase the accuracy and integrity of the payment system.

We have extensive experience with evaluating and developing DRG classification systems. In the 1980's we developed a Pediatric Modified DRG system (PM-DRGs) and since the 1990's have contributed to the research effort for the APR-DRGs. It is

our experience that the APR-DRGs are the most advanced DRG classification system available, yielding the most clinically homogeneous groupings and the greatest predictive power. We therefore believe it provides a sound basis for developing CS-DRGs.

The proposed rule provides a helpful conceptual description of the differences between the APR-DRGs and the existing Medicare DRGs. At the same time, the proposed rule does not provide detailed information about the predictive performance of the proposed CS-DRGs. We believe it is important as part of the decision making process for CMS to provide more information to the hospital field on the predictive power of the proposed CS-DRGs for the Medicare patient population. Specifically, we *recommend* that CMS provide predictive performance information that includes mean values and coefficients of variation for length of stay, charges and costs for each category for both the existing Medicare DRGs and the proposed CS-DRGs, along with a fuller assessment of the relative strengths of each system.

(2) Timing for Implementation of Severity Adjusted DRGs: We *recommend* that any final decision to adopt CS-DRGs or parts of the CS-DRGs system be coordinated with and implemented at the same time as other major IPPS policy changes. This includes any revisions to the costing methodology such as the proposed HSRVcc costing methodology, any changes to outlier methodologies such as the contemplated move to DRG-specific outlier thresholds for calculating relative weights, and any other changes that CMS has indicated it may be considering such as revisions to the IME payment formula or DSH payment formula.

(3) Criteria for Technology Representing Increased Complexity of Treatment: CMS has asked for comments on the criteria it plans to develop for incorporating technologies that represent increased complexity (of treatment) but not necessarily greater patient severity of illness. As a first step, we *request* that CMS identifies the situations where technology represents increased complexity but not necessarily greater severity of illness or at least a representative cross section of such situations, and that CMS share its initial thinking so that all of the commenters can offer comments on the same basic set of criteria.

(4) Changes to CMI From a New DRG System: The proposed rule expresses the view that improved documentation and coding in a severity adjusted DRG system will likely lead to apparent (but not real) increases in CMI, and asks for comments on how to project the likely effect of reporting improvements so that offsetting adjustments can be made to the national average base payment amounts. We are concerned that the proposed rule puts this forward as a proposal without any specifics. We offer two recommendations. *First,* as part of this process CMS should share its specific thinking so that all commenters can offer comments on the same basic set of criteria. *Second,* as part of this process since any projections will be

inexact, CMS should commit to making adjustments in future years' base payment levels to the extent the initial adjustment projections are inaccurate.

(5) DRG-Specific Outlier Adjustments to Relative Weights: The proposed rule expresses the view that it would be appropriate to introduce DRG specific adjustments to the relative weights, in place of the existing across-the-board 5.1% set-aside for outliers. We wish to express *two caveats*. *First*, since hospitals lose a lot of money on outlier patients before they begin to collect 80% of costs which adds further to their losses, the DRG specific outlier adjustments to relative weights must be done in a way to ensure that total payments equal costs for patients in each DRG. In other words, it should not cause DRGs with a large number of outlier patients to be net losers. *Second*, it needs to be done in a coordinated way with all other changes to the IPPS, and not piecemeal.

(6) Approach to Consolidation of Base DRGs and Severity Subgroups and Applicability to Non-Medicare Patient Populations: We have three sets of concerns with the approach to consolidating low volume base DRGs and severity subgroups. The first is a generic concern about the statistical criteria used to make judgments about consolidating low volume categories. The second and third are concerns, our most serious concerns, about the appropriateness of the more aggressive consolidations for pediatric, neonatal, obstetrics, psychiatric and substance abuse patients and the applicability of the CS-DRG classification system for non-Medicare patients.

First, the specific criteria for judging a category to be low volume and potentially unstable is unclear and it seems that more categories may have been consolidated than necessary, giving up clinical and statistical homogeneity unnecessarily. This is especially important if the CS-DRGs are envisioned as part of the basis for evolving efforts toward pay-for-performance where such measures as post-admission complications and readmissions need to be evaluated on a risk adjusted basis. It is also unclear whether instances of apparent instability may be the result of using a very minimalist approach to statistical outliers (only removing patients that exceed 3 standard deviations above both charges per case and charges per day - - - which would be very few patients).

In the one example shown, MDC 11 Kidney & Urinary Tract surgical consolidations for severity subclass (4) patients, most of the consolidated categories had 500-1,000 cases, seemingly enough for stable values, and had average charges that varied from $128,729 to $73,110, seemingly enough to warrant further distinction. It's not clear how the judgment was made that these average charge values were sufficiently similar to consolidate, though one might conjecture that the judgment was made that at the level of the individual hospital there would be very few of these cases and that the consolidated surgical subclass (4) charge value of $107,258 would still represent a substantial improvement over the existing system. This is however just a conjecture. We *request* that CMS provide further information about the criteria and considerations it used to judge

categories as low volume and potentially unstable and to judge the mean charges (or costs) as sufficiently similar to warrant consolidation.

Our *second,* and very serious concern is that regardless of the appropriateness of consolidating certain severity subclass (4) categories for the Medicare program, it would be inappropriate to do so for non-Medicare patient populations. We have analyzed statistical patterns across large, all age national discharge databases and have always found that subclass (4) patient costs are higher for pediatric patients than for older patients. Thus, this approach would systematically disadvantage pediatric patients and hospitals that specialize in their care. We therefore *recommend* that if CMS decides to implement a consolidation strategy for severity subclass (4) patients, that it very carefully qualifies the applicability of this approach to non-Medicare patients, especially pediatric patients (see recommendation for out next concern for further elaboration of this issue).

Our *third* and most fundamental concern is the very extensive consolidation of base DRGs and severity subgroups for DRGs populated predominantly by non-Medicare patients. The consolidations were most extreme for neonatal patients and were also very extreme for obstetrics, psychiatric and substance abuse patients and for certain DRGs geared toward pediatric conditions. The consolidations are most extreme for neonates because the 28 neonatal base DRGs of the APR-DRG system are mapped to fit as closely as possible into the 7 neonatal DRGs of the existing Medicare system and the four tiered severity subclasses are collapsed to just two tiers. The consolidations for obstetrics, psychiatric, substance abuse and selected pediatric DRGs are also very extensive giving up important clinical and cost distinctions for non-Medicare patient populations, but the four tiered severity subclasses are generally maintained. These consolidations result in classifications that are very inadequate and make the CS-DRG system inappropriate for non-Medicare patient populations.

In the past, and most recently in the 5/18/04 proposed rule for Medicare IPPS, CMS has made explicit statements about the intended purpose and uses of the Medicare DRG system. It is critical that as CMS proposes a revamping of the patient classification system for Medicare IPPS, it once again articulates the intended purpose and uses of the classification system. There are two statements from the 5/18/04 Federal Register (Vol.69, No.96, page 28210) pertaining to pediatric and neonatal patients that are particularly relevant. They are as follows:

> "Our primary focus of updates to the Medicare DRG classification system is on changes relating to the Medicare patient population, not the pediatric or neonatal patient populations. However, we acknowledge the Medicare DRGs are sometimes used to classify other patient populations....."

> "We advise those non-Medicare systems that need a more up-to-date system to choose from other systems that are currently in use in this country, or to

develop their own modifications. As previously stated, we do not have the data or expertise to develop more extensive newborn and pediatric DRGs. Our mission in maintaining the Medicare DRGs is to serve the Medicare population....."

Our *recommendation* is that since CMS has approached the development of the CS-DRGs in the same manner as it has maintained the existing Medicare DRGs, with a primary focus on the Medicare population, that it once again very clearly articulate this focus and the applicability of the system for pediatric and neonatal and other non-Medicare patient populations. This will help to avoid a lot of confusion throughout the hospital field.

Attached is a short Technical Appendix with a somewhat more detailed set of highlights explaining why CS-DRGs are not appropriate for non-Medicare patients.

(7) Impact of Refinement of DRG System on Payments: This section of the proposed rule provides helpful information on the impact of the proposed new system, both at the DRG level and the facility level. At the same time, several of the tables provide illustrative information while more comprehensive information is needed. We therefore *request* more extensive information for the following tables:

- Table G, Percent Change in Case Mix Among Medical and Surgical DRGs: This is very helpful, but would be more helpful as an overview table if several other breakouts were provided, such as a breakout for non-O.R. procedure based DRGs (e.g., cardiac catheterization) which have costing patterns different from medical DRGs, a breakout for mental health and substance abuse DRGs and for rehabilitation which show probably the largest changes, and any other DRG subgroupings with a distinctive pattern with the proposed new costing method.

- Illustration (page 24021): The proportion of charges attributable to each cost center is displayed for two DRGs. It would be especially helpful to have a table with this information for all DRGs to better understand how the proposed costing method is working. It would also be very helpful to apply the scaling factors to show the percentage of costs attributable to each cost center for each DRG.

- Table I, Payment Impact from HSRVcc and CS-DRGs by Selected High Volume DRGs: This is a very useful table, but it should include all DRGs. There are many other important patterns not shown, such as the dramatic increases in relative weights for mental health, substance abuse and rehabilitation DRGs that should be displayed, along with a need to view all the DRGs to understand all of the patterns.

II (E) Proposed Recalibration of DRG Weights ("DRG Weights")

CMS is proposing a revised approach for calculating the relative weights for low volume DRGs. CMS is proposing to maintain the same minimum low volume DRG threshold of 10 cases to set weights, but for those DRGs with less than 10 cases CMS is proposing to assign a relative weight based upon the value from an assigned adjacent DRG. CMS has asked for comments on the proposed crosswalk of adjacent DRGs, specifically the 40 DRGs that had less than 10 Medicare cases in this particular year. Of these 40 low volume DRGs, 29 are for 0-17 year old DRGs and 7 are for neonatal DRGs.

The relative weights for low Medicare case volume DRGs are especially relevant to children's hospitals as the federal children's hospital graduate medical education (CHGME) funding program, administered by HRSA, is based off of the Medicare IPPS. NACHRI wishes to request background information on the reason for the proposal and offer specific comments and recommendations regarding the minimum case volume threshold, the proposed crosswalk to adjacent DRGs, the need for updating the relative weights for the neonatal DRGs, and the explanation of the asterisked low case volume DRGs at the end of Table 5.

Our *request* for background information is to ask CMS to explain why it is at this time proposing the revised approach to low volume DRG relative weights. Our understanding is that in previous years the weights for these DRGs were developed with supplemental information from other state data bases. Is the reason for the proposed change that this information is less readily available or that the Medicare IPPS methodologies for costing and payment are sufficiently different that it is difficult to accurately interpolate values from other data sources? It is important to understand this reasoning and the options. The rest of our comments pertain to the best way to implement the proposed new approach if that is indeed the best and most practical approach.

Our *first recommendation,* if a mapping to adjacent DRG approach is to be implemented for low volume DRGs, is to increase the minimum threshold to a level higher than 10 cases. This is far too few to expect stable values especially when combined with a very minimalist approach to removing statistical outliers (must exceed 3 standard deviations above mean for both charges per case and charges per day - - - which will remove very few patients). It is *recommended* that the minimum case volume be increased and also that a blending formula be introduced. Based on our experience working with these situations and a review of Medicare case volumes and relative weights in the 4/25/06 proposed rule, we would put forward the following suggested modifications for version 24.0 Medicare DRGs along with the concept of continuing to monitor and evaluate the approach for future years. Here are the specifics of our suggested approach for V24 Medicare DRGs:

<10 cases: 100% weight from adjacent DRG.

10-29 cases:	25% weight from actual experience; 75% weight from adjacent DRG.
30-59 cases:	50% weight from actual experience; 50% weight from adjacent DRG.
60-89 cases:	75% weight from actual experience; 25% weight from adjacent DRG.
90+ cases:	100% weight from actual experience.

Our *second recommendation* pertains to the selection of adjacent DRGs for low volume DRGs. This is not straightforward because the low volume DRGs don't necessarily line up neatly with another similar DRG and the values for the pediatric and neonatal DRGs, given their heterogeneity, can vary depending on the hospital sample frame they are generated from and the costing methods used to calculate costs. We note that the majority of the weights for DRGs Age 0-17 Years are mapped to DRGs Age >17 Years WO CC, though several are mapped to DRGs Age >17 Years W CC. These mappings are difficult to do and inexact as the weights for DRGs Age 0-17 Years can be somewhere between that of DRGs Age >17 Years WO CC and DRGs Age >17 Years W CC. There are several DRGs, however, that based on our work with other data bases we feel should have their mapping changed to a higher weighted DRG category. They are as follows:

- DRG 3 Craniotomy Age 0-17 Years (2 Medicare cases): Based on our experience working with this DRG on other data bases, we believe that it would be more appropriate to crosswalk DRG 3 to DRG 1 Craniotomy >17 Years W CC than to DRG 2 Craniotomy >17 Years WO CC.

- DRG 163 Hernia Procedures Age 0-17 Years (4 Medicare cases): This is a very heterogeneous category. Unlike patients age >17 Years for which there are four hernia procedure categories, distinguishing both types of hernia repair and the presence of CC, there is just one hernia procedure category for patients 0-17 years. Our experience has been that the weight for DRG 163 calculated from a predominantly general hospital base but with a proportionate sampling of children's hospitals cases, lines up most closely with DRG 161 Inguinal & Femoral Hernia Procedures Age >17 Years W CC, rather than DRG 162 Inguinal & Femoral Hernia Procedure >17 Years WO CC.

If our recommendation is accepted to increase the minimum case volume requirement and implement a blending formula, there will need to be additional crosswalks developed. The Technical Appendix contains the additional recommended crosswalks to adjacent DRGs. We note that these are not perfect crosswalks and are

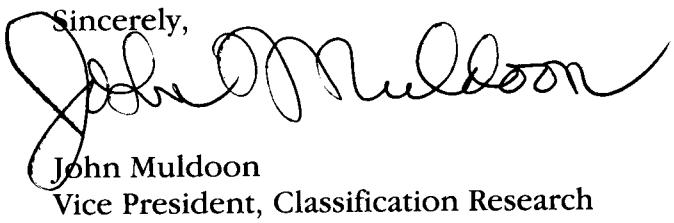
presented following the same general approach proposed by CMS for the 40 DRGs with less than 10 cases.

Our *third recommendation* pertains to the relative weights and lengths of stay values for the 7 neonatal DRGs. The V24 values haven't changed other than for a 1% increase to stay proportional to the rest of the system. This would imply that these values have not been updated to reflect the proposed switch from charge based weights to cost based weights. The switch to cost based weights would likely have a large effect for neonatal DRGs since a very large proportion of the care is for room & board/ nursing services. In addition, it would appear that the weights for the 7 neonatal DRGs haven't been updated since V19 Medicare DRGs other than for ± 1% across the board changes to keep proportional with the overall updates to the relative weights. We therefore *recommend* that an approach be developed to update the neonatal DRG weights and to reflect as closely as practical any changes that are adopted in costing methods.

Our *fourth and last recommendation* is a technical item regarding the relative weights and the geometric and arithmetic mean length of stay values displayed in Table 5, and specifically, the explanation of the asterisks at the end of the table. One of the "Notes" indicates that an asterisk in the gmlos and amlos column indicates there is no data to compute the LOS values. It would also be helpful to add a "Note" explaining what the asterisk alongside the MED/SURG Type means (this seems to mean that the relative weight was developed based upon an adjacent DRG or perhaps from supplementary data sources or methodologies). It would be very helpful to include the minimum case volume threshold in the "Notes" to the table.

NACHRI appreciates this opportunity to submit these comments. If you have any questions about our comments and recommendations or if we could provide further information, please contact me at (703) 684-1355 or jmuldoon@nachri.org.

Sincerely,



John Muldoon
Vice President, Classification Research
NACHRI

Attachment 191

Technical Appendix

Highlights of Why Proposed CS-DRGs Are not Appropriate for Non-Medicare Patient Populations ("DRGs: Severity of Illness") NACHRI June 12, 2006

MDC 15 Newborns and Other Neonates With Problems Arising in the Perinatal Period: Instead of 28 base DRGs and a total of 112 cells with the 4 severity subclasses, MDC 15 is consolidated to 7 base DRGs and 14 cells with a two-way split for each DRG based upon severity 1 & 2 combined and severity 3 & 4 combined. This is very different from all other areas of the CS-DRGs. The neonatal categories from the APR-DRGs are mapped to fit as closely as possible into the existing 7 neonatal Medicare DRGs, with the 4 severity subclasses collapsed to just a two-way split. The neonatal categories of the CS-DRGs provide somewhat more differentiation than the existing Medicare DRGs by virtue of the two-way severity breakouts, but are very far from adequate. Neonatal services are highly regionalized and as a result there is a need for the neonatal DRGs to be among the most refined to minimize systematic risk by hospital type, yet they are among the least developed in the CS-DRG system. Following is a further description of their inadequacies.

Like the existing Medicare DRGs, the CS-DRGs do not differentiate between medical and surgical patients and are structured around overly broad birthweight ranges - - - <1,000 grams (2.2 lbs), 1,000-2,499 grams (2.2-5.5 lbs), and >2,499 grams (5.5 lbs). The <1,000 gram group includes many extremely premature infants who die within 1 to 2 days receiving comfort measures only (especially those in <500 gram and 500-749 gram ranges), together with many extremely premature newborns with lengths of stay of several months and certain prematures who require surgical services and full-term neonates receiving ECMO services.

The 1,000-2,499 gram neonates are broken out into 2 groups, those with major problems and those without major problems. This is far too broad a birthweight range, varying from very premature newborns of 1,000 grams to infants of almost 2,500 grams many of whom are not even gestationally premature. There is also no breakout for medical versus surgical patients. Finally, as a detail point, the base APR-DRG 625 neonate birthweight 2,000-2,499 grams with other significant condition would more appropriately be classified with the "major problem" than the "without major problem" group.

The neonates in the birthweight range >2,499 grams are divided into three groups - - - those with a major problem, those with other significant problem, and those without a significant problem. As elsewhere, surgical patients are not distinguished from medical patients, the four severity subgroups are collapsed to two severity subgroups even though there is a doubling of cost from one severity level to the next, and normal newborns are combined with newborns with other problems - - - patients who are not

extremely sick but have costs about 2 ½ times that of normal newborns.

Pediatric Oriented DRGs: The CS-DRGs consolidates some of the pediatric oriented DRGs that exist in the APR-DRGs. There will be very few Medicare patients in these categories but it is problematic for pediatric patients as they are consolidated into DRGs with considerably lower costs. This includes the APR-DRGs for bronchopulmonary dysplasia, major cardiothoracic repair of heart anomaly, dorsal & lumbar fusion procedure for curvature of back (subclass 4), and neonatal aftercare which is merged into other aftercare and convalescence.

MDC 14 Obstetrics: The CS-DRGs consolidate many of the base obstetrical DRGs from the APR-DRGs so that there are 3 surgical instead of 6 surgical base DRGs, and 3 medical instead of 6 medical base DRGs. There may not be very many Medicare patients in these DRGs, but there are clinical and cost differences that are important to non-Medicare patient populations. For example, the surgical APR-DRG for ectopic pregnancy procedures is consolidated with D&C, aspiration curettage or hysterotomy for OB diagnoses and with other O.R. procedures for OB diagnoses, but represent very different patients and with different costs. On the medical side, the obstetric base DRGs are winnowed down to vaginal delivery, antepartum diagnoses, and postpartum & abortion diagnoses without any distinctions for different kinds of antepartum or postpartum conditions.

MDC 19 Mental Health: The CS-DRGs consolidate 11 medical base DRGs from the APR-DRGs to just 3 medical base DRGs. Perhaps the impact is not as great for the Medicare population, but for the non-Medicare population this gives up clinical distinctions and length of stay/cost differences that are important. We are particularly concerned about merging childhood behavioral disorders and eating disorders into other mental health disorders which contain patients from six different APR-DRGs.

MDC 20 Substance Abuse: The CS-DRGs consolidate the 6 substance abuse base DRGs from the APR-DRGs into just 2, one for substance abuse/left against medical advice and one for all the rest of the DRGs. As with the mental health DRGs, perhaps the impact is not as great for the Medicare population, but for the non-Medicare population this gives up clinical distinctiveness and length of stay/cost differences that are important. Of note are the longer stays for alcohol & drug dependence with rehabilitation/detoxification therapy and the somewhat higher costs for the higher severity alcohol abuse & dependence patients compared to other drug abuse patients.

Additional Recommended Crosswalks to Adjacent DRGs for Low Case Volume DRGs ("DRG Weights")

- DRG 26 Headache & Seizure Age 0-17 Yrs (24 Medicare cases) → DRG25 Headache & Seizure Age >17 Yrs WO CC.

- DRG 70 Otitis Media & Upper Respiratory Infection Age 0-17 Yrs (23 Medicare cases) → DRG 69 Otitis Media & Upper Respiratory Infection Age >17 Yrs WO CC.

- DRG 71 Laryngotracheitis (71 Medicare cases) → DRG 70 Otitis Media & Upper Respiratory Infections Age 0-17 Yrs.

- DRG 91 Simple Pneumonia & Pleurisy Age 0-17 Yrs (53 Medicare cases) → DRG 90 Simple Pneumonia & Pleurisy Age >17 Yrs WO CC.

- DRG 98 Bronchitis & Asthma Age 0-17 Yrs (13 Medicare cases) → DRG 97 Bronchitis & Asthma Age >17 Yrs WO CC.

- DRG 184 Esophagitis, Gastroent & Misc Digest DX Age 0-17 Yrs (76 cases) → DRG 183 Esophagitis, Gastroent, & Misc Digest DX Age >17 Yrs WO CC.

- DRG 190 Other Digestive System DX Age 0-17 Yrs → DRG 189 Other Digestive System DX Age >17 Yrs WO CC. Note DRG 190 is difficult to map as it is close to half way between DRG 188 W CC and DRG 189 WO CC, but with the proposed blending formula the final weight would actually come out about half way between DRGs 188 and 189.

- DRG 212 Hip & Femur Procedures Except Major Joint Age 0-17 Yrs (10 cases) → DRG 211 Hip & Femur Procedures Age >17 Yrs WO CC. Note, the relative weight from the 10 Medicare cases is noticeably low, but with the proposed blending formula the final weight would probably be close to what would be obtained from larger case volume.

- DRG 322 Kidney & Urinary Tract Infections Age 0-17 Yrs (67 cases) → DRG 321 Kidney & Urinary Tract Infections Age >17 Yrs WO CC.

- DRG 327 Kidney & Urinary Tract Signs & Symptoms Age 0-17 Yrs (11 cases) → DRG 326 Kidney & Urinary Tract Signs & Symptoms Age >17 Yrs WO CC.

- DRG 396 Red Blood Cell DX Age 0-17 Yrs (20 cases) → DRG 395 Red Blood Cell DX Age >17Yrs.

- DRG 417 Septicemia Age 0-17 Yrs (33 cases) → DRG 416 Septicemia Age >17 Yrs.

- DRG 422 Viral Illness & Fever of Unknown Origin Age 0-17 Yrs (77 cases) → DRG 421 Viral Illness Age >17 Yrs.

192

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June 12, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445
200 Independence Avenue SW
Washington, DC 20201

Re: CMS-1488-P
Intractable Migraine and the DRG System

Dear Dr. McClellan:

I am pleased to submit these comments with respect to the proposed FY 2007 hospital IPPS rule on behalf of the Michigan HeadPain and Neurological Institute ("MHNI") of Ann Arbor, Michigan. MHNI is a tertiary care center of excellence treating, often on referral from other sophisticated academic and specialized centers, some of the country's most difficult migraine cases. MHNI physicians work in concert with a dedicated hospital inpatient unit that also specializes in treating complex migraine and other pain disorders. The existing DRG classification system does not adequately account for severity of illness in some types of migraine cases, and we urge you to take account of this experience as you consider very significant changes to the DRG payment system for implementation in future years. MHNI specialists would welcome the opportunity to supplement these comments through further communications with you and your staff.

"DRGs: Severity of Illness"

The current DRG classification system recognizes three separate DRGS for inpatient headache cases, two (DRGs 24 and 25) for adults and one (DRG 26) for pediatric cases. All three include seizure as well as headache. DRG 24 (with complicating conditions) which would generally be used for the most complex migraine cases, has a proposed weight of only 1.0388 and a geometric mean length of stay ("LOS") of only 3.5 days. As such, it does not begin to capture the severity of illness typical of the most complex intractable migraine cases seen at referral centers like MHNI.

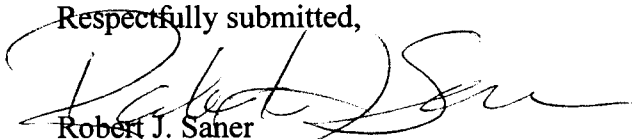
Intractable migraine cases seen on an inpatient basis fall into two broad categories with very different complexity, LOS, and associated hospital costs and charges. The first type, commonly referred to as "intravenous therapy class headache," generally respond to IV therapy rapidly, resulting in a short LOS and much lower hospital costs; in many such cases, the migraine incident terminates in the ER or HOPD without ever requiring admission.

The second type, "status migrainosus" or "protracted migraine not easily terminated," has quite different characteristics, and inpatient treatment is much more complex and costly. Many of these patients are suffering the effects of medication overuse headache ("MOH"), also referred to as "medication rebound headache." International Headache Society Criteria, 2004. These cases are much more likely to include confounding behavioral or psychological conditions that also must be addressed during an inpatient stay, lest the effort will fail. .

In recent years, specialists at programs like MHNI have seen a marked increase in admissions of patients suffering adverse effects from prolonged use of narcotics. To effectively treat underlying symptoms, these patients must simultaneously undergo withdrawal and aggressive IV treatment on a medically supervised inpatient basis, the effects of which can include temporarily escalating migraine, nausea, insomnia, severe emotional distress and other symptoms. This is why these patients cannot be successfully treated as outpatients. LOS for these patients is much longer, measured at least in days and sometimes weeks. Freitag FG, Lake AE III, Lipton R, Cady R, Diamond S, Silberstein S. U.S. Headache Guidelines Consortium, Section on Inpatient Treatment. Inpatient Treatment of Headache: An Evidence-based Assessment. *Headache* 2004; 44(4):342-60; Saper JR, Lake AE III, Madden SF, Kreeger C. Comprehensive/tertiary care for headache: A 6-month outcome study. Headache 1999; 39:249-263.

The current DRG classification should be adjusted to address these more complex and costly cases. One approach would be better recognition of drug dependence and addiction as a complicating condition for DRG 25. Another would be bi-furcation of DRG 25 into two or more new DRGs. Alternatively, if CMS proceeds to move to a new classification system based on APR DRGs or consolidated severity adjusted DRGs, these mechanisms should be tested prior to implementation to insure that they adequately capture through their respective severity adjusters the nature of these most difficult migraine patients. MHNI would be pleased to work with CMS staff to insure that the experience and data generated at programs like MHNI are available to you in designing appropriate improvements to the currently flawed classification system.

Respectfully submitted,



Robert J. Saher
Counsel for Michigan HeadPain and
Neurological Institute

CC: Michigan HeadPain and Neurological Institute

Recd via e-mail to CMM 193

June 12, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
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Washington, DC 20201

File Code CMS-1488-P: Comments Related to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

St. Jude Medical, Inc. appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS) proposed changes to the Medicare hospital inpatient prospective payment systems and fiscal year 2007 rates (CMS-1488-P), (hereinafter referred to as "Proposed Rule" or "NPRM"). St. Jude Medical is dedicated to making life better for cardiac, neurological and chronic pain patients worldwide through excellence in medical device technology and services. Our product portfolio includes implantable cardioverter defibrillators (ICDs), pacemakers, electrophysiology catheters, vascular closure devices, heart valve replacement and repair products, and spinal cord stimulation.

The Proposed Rule seeks to both create and implement the most significant and complex changes in Medicare reimbursement since the Hospital Inpatient Prospective Payment System (IPPS) was implemented more than 20 years ago. It does so in just one regulatory cycle, providing stakeholders only one 60 day comment period to review the regulation, analyze the methodological changes and provide input. The magnitude of the proposed changes is immense, as the Proposed Rule contains a previously unseen methodology that combines cost-based weights with hospital-specific weights into one Hospital-Specific Relative Value cost-center weights proposal (HSRVccs). CMS's inclusion of a consolidated severity-adjusted diagnosis-related group (CS-DRG) model adds a layer of complexity, with the potential for implementation in either FY 2007 or 2008.

The details of these complex proposals were neither discussed nor scrutinized in any public forum prior to the release of the Proposed Rule. Nor was any analysis provided to validate that the proposed changes result in more accurate payment.

St. Jude Medical supports movement toward improved accuracy under the inpatient prospective payment system (IPPS) and appreciate that CMS has worked hard to propose changes in an effort to improve the system. However, we do not believe that the proposed recommendations solve the existing problems nor are they ready for implementation in FY 2007.

Due to the magnitude of the changes, the lack of complete information to fully assess the proposed changes, and the importance of improving the accuracy of the payment rates, St. Jude Medical supports the following:

- **Maintaining the current methodologies for assigning DRG relative weights and determining patient classifications in FY 2007. Although St. Jude Medical supports CMS' goal of improving the accuracy of the IPPS, our analysis raises significant questions about CMS' approach and further analysis should be conducted before any changes to the current system are made.**

- **Implementation of cost-based weights in FY 2008 provided that:**
  - **CMS' methodology is analogous to the methodology that is currently used in the outpatient PPS system.**
  - **CMS makes changes to the cost reports that would result in significantly improved timeliness and accuracy of the information used to calculate estimated costs. To determine methods of improving hospital cost reports, CMS should assemble an expert panel or work group comprising hospital financial experts, prospective payment authorities, hospital charge master personnel and other experts. This group could make timely recommendations on how to refine the cost reports to yield more accurate and timely data that may be used in setting PPS weights.**
  - **CMS makes a full adjustment for charge compression. A proposed methodology to counterbalance the effects of charge compression is addressed in this letter.**

- **A DRG classification methodology that accounts for patient severity of illness, complexity and patient benefit. These refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. St. Jude Medical recommends that**

CMS start with the current DRG system and provide overlays for severity, complexity and patient benefit.

- **Simultaneous implementation of revised cost-based weights and severity-adjusted DRGs. Making these changes simultaneously would minimize swings in payment rates for many DRGs.**

- **A three-year transition with a blend of charge-based DRG weights and the new cost-based DRG weights or, as an alternative, dampening the reduction for DRGs with significant decreases in the relative weights similar to the dampening of APC weights in the outpatient department.**

Regardless of the IPPS changes that CMS ultimately implements or the timeframe in which those changes are implemented, we believe that the following issues are of paramount importance and need to be addressed:

- **The hospital-specific, relative value methodology ignores any hospital-level variation that is not explained by the PPS case-mix index, which may include meaningful and valid cost variations. If certain services are provided predominately in hospitals with higher average costs, this method will produce lower DRG weights for these services. If legitimate costs are not recognized, Medicare beneficiaries' access to care may be diminished.**

- **Using 10 cost-center groupings within the Hospital Specific Relative Values (HSRVs) to calculate DRG relative weights ignores detailed data in the cost reports that could be used to derive a more accurate set of weights. This will exacerbate many of the more problematic aspects inherent in the use of weights based on estimated costs, including data lags, data omission and charge compression.**

- **CMS proposes to implement a new severity-adjusted, patient classification system in 2008 or earlier. However, the Proposed Rule models the impact of these changes using FY 2004 inpatient claims, instead of the FY 2005 inpatient claims used to model the estimated cost-based DRG weight changes. This discrepancy, and the fact that CMS did not make the new patient classification system software (the "grouper") available when the regulation was released, made it impossible to accurately assess the impact of both changes from tables provided in the Proposed Rule.**

- **When calculating payment weights, CMS did not use standard methods to weight hospital payment data and trim Medicare claims data. CMS omitted data from 238 hospitals, representing 25 percent of routine hospital charges.**

This omission and failure to apply appropriate weights significantly decreased the payments for technology-intensive cases.

Following are detailed comments that further explain our concerns and recommendations on the proposed DRG weights and classification system changes.

1. COST-BASED WEIGHTS AND COST REPORTS ("HSRV Weights")

St. Jude Medical supports the goal of improving accuracy within the IPPS. Before CMS implements an estimated cost-based payment system, it should address a number of significant concerns raised by the use of cost-based weights. Estimated cost-based weights would be derived, in part, from Medicare cost reports, which were not designed for use in a prospective payment system. The cost reports are a vestige of the "reasonable cost" based reimbursement system that was implemented when Medicare began in 1966. When the hospital inpatient prospective payment system was implemented in 1983, hospitals began to be paid a fixed amount based on the patient's diagnosis, rather than incurred costs. Under IPPS, reimbursement became independent of the actual costs incurred, and the cost report no longer played a key role in the reimbursement received by hospitals, with some limited exceptions for items such as bad debt, graduate medical education, pass-through, or outlier payments.

There are several serious problems in using cost reports to derive estimated costs which are then used to calculate DRG relative weights that should be carefully considered and addressed. These include: 1) the accuracy of the cost-report data; 2) the overall timeliness of the cost report data; 3) the omission of data on new technologies; 4) comparability of costs reports due to variability in how hospitals allocate costs; and 5) the compression of the weights both across and within cost centers.[1] [2] [3]

Accuracy of Cost Report Data. CMS' cost-based weights are calculated by applying cost to charge ratios reported in hospital Medicare Cost Reports to charges for specific cases. To a considerable extent, the accuracy of cost-based relative weights depends on the accuracy of the costs in the Medicare Cost Report. The cost report, however, was not designed to measure case-specific costs. Instead, it was designed to measure a hospital's

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[1] J. Ashby, "The Accuracy of Cost Measures Derived from Medicare Cost Report Data," Intramural Report I-93-01, March 1993; MedPAC, "Sources of Financial Data on Medicare Providers," Report to Congress, June 2004.

[2] Cost-based weights would further exacerbate the problem of "charge compression," which has been observed in the early years of IPPS (when cost-based weights were used) as well as in a number of studies and in the current OPPS. AdvaMed has conducted a study that documents the effects of charge compression using current MedPAR data.

[3] A 1998 study by MedPAC's predecessor, ProPAC noted concerns with cost report data such that "cost report data may, in some cases, produce imprecise DRG weights." ProPAC further noted that the "Secretary [of HHS] should verify the accuracy of cost report data and implement changes as necessary."

aggregate cost as defined by Medicare regulations. The limitations of the Medicare Cost Report as a cost determination tool are well documented in the literature.

A new report (June 2006) by Henry Miller, Ph.D., Navigant Consulting Inc., details problems in the use of the Medicare Cost Report to calculate DRG relative weights. [4] Miller states: "Although the approach is sufficient to meet the original purpose of the cost report, i.e., calculation of Medicare reimbursable cost, it does not provide accurate data for the calculation of unit costs or for setting DRG weights."

The report, similar to a 1992 report Miller completed for ProPAC (MedPAC's predecessor), addressed the accuracy of using the CMS approach to calculating and applying cost to charge ratios in the development of DRG weights. In this new report, DRG-specific costs calculated by more than twenty hospitals that used sophisticated cost accounting systems for internal reporting were compared to Medicare DRG payment that had been made in the past and that which would be made under the proposed regulations. The cost accounting systems used standard costing based on management engineering studies conducted to determine the precise inputs used in specific services and the costs of those inputs.

Findings for six key cardiac DRGs that include implantation of pacemakers and defibrillators are presented in two primary comparisons; a comparison of the cost per case by DRG based on cost accounting data compared to cost per case calculated using cost-to-charge ratios (CCRs). The second comparison is an estimate of the profitability by DRG based on comparing Medicare payments for specific DRGs to hospital costs for these DRGs derived from hospital cost accounting systems. In both instances, comparisons were made for the same period, i.e., the cost accounting data was collected for the period that matched hospital fiscal years used for cost reports.

Miller found that the use of CCRs to calculate costs consistently and significantly understates costs for DRGs that include implantation of pacemakers and defibrillators. The percent difference in costs averaged 28.8 percent. The findings are presented in the table below:

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[4] Miller, H. *Issues In The Use Of Medicare Cost Reports To Calculate DRG Relative Weights*, Navigant Consulting June 5, 2006.

Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk	$ 22,291	$ 16,740	$ 5,551	25%
116 Oth Perm Cardiac Pacemaker Impla	$ 15,438	$ 11,069	$ 4,369	28%
118 Pacemaker Dev Replacement	$ 12,160	$ 8,265	$ 3,895	32%
515 Cardiac Defib Impl W/O Cath	$ 35,511	$ 25,347	$ 10,164	29%
535 Car Defib Impl w Cath AMI	$ 47,089	$ 33,165	$ 13,925	30%
536 Car Defib Implant wo AMI	$ 41,602	$ 29,570	$ 12,032	29%

Miller calculated profitability for each of the same DRGs by calculating payments based on 2004 charge-based weights and comparing them to 2004 hospital costs, measured using cost accounting data. As can be seen in Table 5.3, hospitals are incurring substantial losses for each of the cardiac DRGs of interest under CMS' current charge-based approach for calculating DRG weights.

When Miller calculated profitability based on the cost-based weights in the proposed rule, losses on cardiac DRGs increased from an average of 20.0 percent for charge-based weights to an average of 38.2 percent under the proposed cost-based weights. The findings are presented in tables below:

Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk	$ 18,410	$ 22,291	$ (3,881)	-17%
116 Oth Perm Cardiac Pacemaker Impla	$ 12,246	$ 15,438	$ (3,192)	-21%
118 Pacemaker Dev Replacement	$ 8,352	$ 12,160	$ (3,808)	-31%
515 Cardiac Defib Impl W/O Cath	$ 27,703	$ 35,511	$ (7,808)	-22%
535 Car Defib Impl w Cath AMI	$ 41,781	$ 47,089	$ (5,308)	-11%
536 Car Defib Implant wo AMI	$ 32,587	$ 40,163	$ (7,576)	-19%

Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk**	$ 13,673	$ 22,291	$ (8,618)	-39%
116 Oth Perm Cardiac Pacemaker Impla**	$ 9,173	$ 15,438	$ (6,265)	-41%
118 Pacemaker Dev Replacement	$ 7,185	$ 12,160	$ (4,975)	-41%
515 Cardiac Defib Impl W/O Cath	$ 21,466	$ 35,511	$ (14,045)	-40%
535 Car Defib Impl w Cath AMI	$ 30,513	$ 47,089	$ (16,576)	-35%
536 Car Defib Implant wo AMI	$ 27,018	$ 40,163	$ (13,145)	-33%

** Several DRGs were reorganized in the proposed rule. Under the proposed rule, cases that were grouped in DRG 115 are grouped in DRG 551; cases that were grouped in DRG 116 are grouped in DRG 552.

The report found that the use of cost report data results in substantial inaccuracies in the calculation of costs of specific DRGs. When costs based on cost reports are compared to actual costs measured by hospitals for the DRGs that were studied, differences as great as 41 percent were measured with an average difference of approximately 30 percent. These differences increase losses already incurred by hospitals for many of the DRGs studied. If the proposed cost-based weights are implemented, hospitals will receive as little as 60 percent of their costs for some DRGs.

Miller's 2006 report reached the same conclusion as his 1992 ProPAC report. Both reports identified substantial variances between costs calculated by hospital accounting systems and costs calculated using Medicare cost reports which lead to the conclusion that the Medicare Cost Report did not necessarily provide accurate measures of cost, especially when it was used to calculate the cost of specific services.

The Navigant report has been attached as part of St. Jude Medical's comments.

Overall Timeliness of Cost Report Data. The cost report data are old, significantly older than the charge based data currently used to determine payment weights under the IPPS. In the current system, the DRG weights are calculated using claims that are 2 years older than the payment year. Under an estimated cost-based IPPS system, the DRG weights are calculated using cost report data that is 3 to 4 years older than the payment year. The quality of the information is reduced because it is outdated. The use of estimated cost-based weights requires matching billed charges from over 13 million hospital claims to cost reports for each individual hospital. Under the estimated cost-based system in the Proposed Rule, CMS used hospital claims data from FY 2005, and hospital cost reports from FY 2003. St. Jude Medical supports an approach that uses the most recent claims data available.

Omission of Data on New Technologies. Inherent lags between the time period covered by the cost reports and the payment year mean that recent important medical technology advances are omitted from the costs, which in turn determine the CCRs that are used to calculate cost-based DRG weights. Data that are three to four years old would exclude many of these technological advances in the calculation of CCRs. This will translate into reduced accuracy in DRG weights.

The current charge-based system, if continued through FY 2007, would use FY 2005 hospital claims data to set the IPPS DRG weights. Switching to cost-based weights would entail the use of cost report data from FY2003 and new technologies that were approved for use subsequent to 2003 would not be reflected in the cost report data. The

use of estimated cost-based weights thus induces greater systemic bias against newer technologies by omitting them from the cost report data and the rate calculations.

Compression of Charges Within Cost Centers. CMS uses hospital CCRs to covert charge data into estimated costs of individual items and services. CMS uses a single CCR for the many items and services in a single department. This process assumes that hospitals apply the same uniform percentage mark-up when setting the charges of each item in the department. Many observers have noted that hospitals do not act this way, but instead use a lower percentage mark-up for high cost items than they use for lower cost items. Hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock"[5]. If hospitals do not use a constant percentage mark-up for items in the department, methodologies that rely on uniform CCRs underestimate the cost of more expensive items and overestimate the cost of less expensive ones, resulting in a systematic distortion of the estimated costs, and of prospective payment rates.

Recent research showed statistical evidence for this type of charge compression in Medicare claims data.[6] The researcher found a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the fraction of cases with high-cost devices increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the researcher also showed that cases with very high device and supply charges led to a stronger impact on the device and supply CCR. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over $30,000) was associated with a much larger increase in the average device and supply CCR than was a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over $20,000), which in turn had a stronger impact than a one-unit change in the lowest measure (device and supply charges exceeding 15,000). These results are consistent with previous analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.[7]

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[5] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

[6] C. Hogan, Direct Research LLC., March 2005. Significantly, this study was conducted exclusively on Medicare claims data with no use of external data.

[7] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for

2. HSRVcc METHODOLOGY CONCERNS ("HSRV Weights")

St. Jude Medical does not support the use of the HSRVcc methodology in the Proposed Rule because it exacerbates many of the problems that are otherwise present with the use of estimated cost-based weights. Under HSRVccs, CMS calculates charge-based weights for each hospital at the cost center level. It is important to note that the HSRVcc methodology proposed by CMS differs both from what MedPAC proposed and from how CMS calculates *cost-based* weights for the outpatient prospective payment system. St. Jude Medical believes that the CMS methodology produces inaccurate and distorted DRG weights due to at least four major deficiencies.

- First, the cost (revenue) centers are collapsed from the full set of at least 37 cost centers into only 10 centers.[8] Although each of the 37 cost centers has a unique CCR, the CMS grouping methodology employs only 10 CCRs. This approach essentially throws out detail that is available on the cost report and that CMS uses in calculating the outpatient prospective payment system rates. St. Jude Medical is concerned that CMS disregards information that would increase accuracy and does so as part of an initiative intended to improve accuracy.

- Second, the national CCR approach eliminates the specificity of CCRs for supplies and equipment in individual hospitals that perform more procedures involving implantable devices. These hospitals in general have higher CCRs for supplies than other hospitals, and using the hospital-specific CCR for supplies and equipment instead of the national CCR better reflects the mix of patients in the hospital and the accompanying costs. [These hospitals still experience charge compression for implantable devices and an adjustment to address this issue (described below) is important in any move to cost-based weights.]

- Third, the HSRVcc methodology proposed by CMS contains two serious mathematical flaws that affect the DRG weights very materially. These methodological problems have a large impact on the relative weight calculations at the DRG level. **Correcting these flaws will have a significant impact on hospital-level payments and hospitals that may have assumed that their payments would increase, may see reductions.** The examples below show, for key DRGs, how these methodological problems affect the DRG weights and, therefore, hospital payments.

Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

[8] CMS's HSRVcc methodology uses two cost centers for routine services (routine days and intensive care services) and eight for ancillary services (drugs, supplies and equipment, therapeutic services, operating room, cardiology, laboratory, radiology, and other services and charges).

IMPACT ON SELECTED DRGs OF HSRVcc		CMS Published	Corrected
558	Percutaneous Cardiovascular Proc w Drug-Eluting Stent w/o MCV Dx	-35%	-21%
557	Percutaneous Cardiovascular Proc w Drug-Eluting Stent w MCV Dx	-26%	-15%
125	Circulatory Disorders Except AMI, w Card Cath w/o Complex Diag	-28%	-20%
124	Circulatory Disorders Except AMI, w Card Cath & Complex Diag	-19%	-14%
535	Cardiac Defib Implant w Cardiac Cath w AMI/HF/Shock	-26%	-16%
536	Cardiac Defib Implant w Cardiac Cath w/o AMI/HF/Shock	-25%	-13%

The HSRVcc is a complex calculation that begins with calculating charge-based weights for each cost center for each DRG every hospital. At this stage, CMS has 10 hospital-specific, charge-based weights for each DRG – one such weight for each of the 10 collapsed cost centers. Next, CMS combines these hospital-specific charge-based weights for each cost center for each DRG to get a set of 10 national charge-based weights for each cost center for each DRG. In computing the national weights for each cost center for each DRG, CMS properly weighted each individual hospital number by the hospital's count of cases in the DRG.

Both of the major flaws occur in the final phase of determining the DRG weights. In this stage, CMS is combining the 10 cost center weights to get a single weight for each DRG and simultaneously converting from charge-based to cost-based weights. Both flaws arise as CMS calculates national CCRs to use in converting charges to costs.

Flaw #1: In calculating the national CCRs, CMS severely over-trimmed the data and threw out hospitals with CCRs for routine days with a value less than 0.26. These CCRs appear to be real and valid, however. They apply mostly to about 238 very large hospitals that contribute roughly one-quarter all routine day charges. In dropping them, CMS is not only throwing out a large amount of valid data, but it is distorting the results by omission of such a significant segment of hospitals with a unique pattern of CCRs. This problem is compounded because CMS retained these hospitals for other steps in calculating the national DRG weights. The table below shows the impact of CMS' trimming.

Trimming of Routine Accommodation Charge Per Day				

CMS CCR trim action	Hospitals	Charges ($ in billions)	Days (in millions)	Charge per Day
Not Trimmed	3133	$ 34.11	39.1	$ 873
Trimmed	238	$ 12.37	3.3	$ 3,723
Total	3371	$ 46.48	42.4	$ 1,097
Source: Direct Research. Ltd. estimate based on 2003 cost reports matched to edited 2005 MedPAR file.				

Flaw #2: In calculating the national CCRs for each of the 10 cost centers, CMS uses the geometric mean of the individual hospital CCRs, after they are erroneously trimmed as discussed above. CMS' calculation of the national CCRs does not account for the volume of charges and costs across hospitals. It is important to note that similar calculations in other CMS prospective payment systems and fee schedules use an appropriate weighting methodology rather than counting each hospital equally. Only with appropriate weighting will the calculated number actually equal the overall national average. In this case, weighting should be based on the aggregate amount of charges in each hospital. Specifically, national CCRs should be calculated using the charge-weighted arithmetic mean. As shown in the table below, the flaw causes a substantial over-estimate of the aggregate national level of costs incurred by prospective payment system hospitals. Costs are so overstated that compared to actual payments on the MedPAR file, hospitals would be losing $23 billion dollars, or about 29 percent, on care provided to Medicare beneficiaries. We know from MedPAC and CMS reports that this is not true and that hospitals experience a small positive margin on inpatient care provided to Medicare beneficiaries. Consistent with this fact, the correct weighting methodology provides an estimated patient care margin of 2.2 percent, as shown in the below table.

	With CMS CCRs	With Charge-Weighted CCRs
Total charges on MedPAR file ($B)	$ 315	$ 315
Estimated raw cost (charges x CCRs, ten categories, $B)	$ 134	$ 107
Estimated 2005 cost (raw cost x 0.92 to account for 2003 CCR vs 2005 charges, $B)	$ 123	$ 98
Actual 2005 payment on MedPAR file, $B.	$ 100	$ 100
Estimated 2005 payment-to-cost ratio	0.812	1.022

The combined impact of the two flaws significantly decreases the payments for technology intensive cases as noted above. St. Jude Medical strongly urges CMS to fix these problems if it continues to use the HSRVcc methodology.

- Fourth, the HSRV is unnecessary, compresses the DRG weights, and particularly and unjustifiably cuts payment rates for cardiac care. Under the current standardization methodology, DRG weights are set by determining the average per-case standardized charges or costs in a DRG across all hospitals and dividing that figure by the average per-case standardized charges or costs for all cases in the DRG system. The key is that the weights are based on pooled charges or costs from across all hospitals nationally. This helps to assure appropriate valuation of all services, including services which tend to be highly concentrated in limited centers, such as cardiology services.

  Under HSRVs, rather than pooling charges or costs across hospitals, CMS first creates relative weights from the charges or costs within each hospital for each DRG to get a hospital-specific weight and then averages those hospital-specific weights across all hospitals (using a case-weighted average) to arrive at a single weight for each DRG. In this manner, average charges or costs in a particular DRG are compared with average charges or costs in each hospital rather than with average charges or costs across all hospitals. The HSRV methodology reduces the weights for DRGs that are performed predominantly in hospitals with higher average charges or costs. This is true even if the costs are valid and if these hospitals are the only hospitals where the particular services are performed.

  The current standardization methodology recognizes that hospital-level variations should not be ignored just because they cannot be explained. In throwing out otherwise unexplained variation in hospital-level costs or charges, the HSRV methodology risks ignoring meaningful and valid cost variations. To the extent that certain services are provided predominantly in hospitals with higher average costs, the HSRV methodology predictably will result in lower DRG weights for these services. If these hospitals' legitimate costs are not recognized, Medicare beneficiaries' access to care for these services could be jeopardized.

  St. Jude Medical strongly believes that HSRV is unnecessary and inappropriate under cost-based weights. If under cost-based weights the cost of care in each DRG has been estimated as accurately as possible, then it is not sound policy to ignore part of what was estimated, as occurs under HSRV. St. Jude Medical recommends that HSRV be dropped and that costs or charges be standardized using the current methodology. If CMS wishes to remove other sources of cost variation from calculation of the DRG, the standardization process could be expanded to include other factors beyond wage index, indirect teaching and disproportionate share. Such

a factor-specific approach would lead to more precise and valid adjustments than the "black box" approach of HSRV.

There are several excellent research studies on the impact of the hospital-specific relative value methodology and, though many of these date from the early 1990's, their findings are remarkably consistent with the impact of HSRV in the proposed rule. In general, the HSRV approach tends to lower relative weights for the higher weighted DRGs and reduce the range of DRG weights between the lowest and highest weighted DRGs. Since the inception of the Medicare inpatient prospective payment system, such compression of the DRG weights has been a closely watched issue due to concern that patients might experience reduced access in the higher cost DRGs if compression became a problem and the DRG weights were too low for high cost cases. Finally, considering type of service, research has consistently shown that cardiology services would be hit especially hard by a change to HSRV. In fact, for hospitals that lose under HSRV, they lose more on cardiology services than they lose overall (they make up some of their cardiology losses on other services). Earlier research found that about 83 percent of hospitals losing under HSRV engaged in cardiac surgery compared to 5 percent for other hospitals.

Cardiology services, especially interventional cardiology services, are performed primarily in the type of hospitals that are disadvantaged by the HSRV methodology. Hospitals performing cardiology services tend to mark up their charges for those services less than they mark up their charges for other services. Hospitals performing cardiac surgery charge more than average for typical cases, therefore their charges for the very expensive cardiac cases are down-weighted in calculating the HSRV weights. In addition, surgical cardiac services tend to be higher weighted services and thus are disadvantaged by the compression of the DRG weights that is a hallmark of the HSRV methodology. These collective effects cause particular disadvantage to cardiac surgery and interventional cardiology services.

Clearly, adopting HSRV is a policy choice with significant implications for hospitals. We seek opportunities to work with CMS to assure that services are paid appropriately and that patient access to these life-saving services and technologies is not diminished. We strongly believe that changes in the proposed rule are necessary both to preserve access to care and to continue to encourage the technological innovation and adoption of new technologies that has brought substantial reductions in mortality and morbidity for patients.

3. CHARGE COMPRESSION (*"HSRV Weights"*)

To determine the cost of individual items and services, CMS generally takes hospitals' charges for an individual item or service and converts them to an estimated cost.

Specifically, CMS converts charges to costs by "backing out" the average mark-up calculated for each department. Thus, if a department had an average mark-up in which charges averaged twice the department's costs, then a charge of $1,000 would be reduced to a cost of $500.

Basing the estimate of the cost for each item and service on the average mark-up in a particular department implicitly assumes that hospitals apply the same percentage mark-up to set the charge level of each item in the department. Many experts and studies have noted, however, that hospitals generally do not apply a uniform percentage mark-up and that, in fact, the percentage mark-up for high cost items is significantly less than the one used for lower cost items. According to a study commissioned by MedPAC, hospitals may reduce the mark-ups for higher-cost items to avoid "sticker shock."[9] This phenomenon is called charge compression. To the extent that charge compression is present, the current CMS rate-setting methodology underestimates the cost of more expensive items and over-estimates the cost of less expensive ones, resulting in a systematic distortion of prospective payment rates.

Charge compression occurs when items with different markups are combined in the same cost center. The HSRVcc methodology would combine estimated costs into only 10 cost centers nationally, increasing the variation of items placed in a particular cost center. Modeling of the HSRVcc methodology confirms that the degree of charge compression inherent in the use of cost-based weights in exacerbated under the HSRVcc methodology.

To examine further the empirical evidence of charge compression, the Advanced Medical Technology Association (AdvaMed) recently commissioned research to investigate whether Medicare claims data provided statistical evidence of charge compression. The results indicated a strong statistical relationship between a hospital's case-mix and the device CCR. Specifically, the study found that there is a statistically significant positive relationship between the device and supply case mix (the fraction of cases with high-cost devices) and the estimated device and supply cost center CCR in a given hospital. As the device case-mix increased, the CCR also increased, indicative of a lower average mark-up. Significantly, the research also showed that basing the case-mix index on the percentage of cases with higher device and supply charges led to a stronger impact. A one-unit increase in the fraction of cases with very high cost devices (device and supply charges over $30,000) is associated with a much larger increase in the average device and supply CCR than is a one-unit change in the fraction of cases with moderate- to high-cost devices (device and supply charges over $20,000), which in turn has a stronger impact than a one-unit change in the lowest measure (device and supply charges exceeding 15,000). The results of this research are consistent with previous

[9] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106

analyses demonstrating charge compression in hospitals' billing patterns for high cost devices and drugs.[10] It is significant that this study was conducted exclusively on Medicare claims data with no use of external data.[11]

4. An Alternative Cost-Based Method (*"HSRV Weights"*)

St. Jude Medical supports efforts to improve the accuracy of inpatient hospital payments. The HSRVcc methodology is too complex, omits important data, and results in a systematic bias against the hospitals that provide patients access to many medically advanced technologies. Rather than improving the accuracy of the payments, it further distorts payments by using a distorted estimate of costs. If CMS chooses to move to a cost-based payment system, we recommend a cost-based payment methodology similar to the one used to calculate the hospital outpatient prospective payment rates.

To calculate hospital outpatient prospective payments, CMS matches outpatient hospital claims to Medicare costs reports using hospital-specific CCRs to determine estimated costs for each hospital encounter. These are then combined to determine the payment rates after adjusting for certain factors. While there are several problems associated with the hospital outpatient PPS, the general methodology of adjusting the most recent claims data using hospital specific and department specific CCRs could be used for inpatient hospital payments.

We support using a modified version of the OPPS methodology in determining cost-based relative payment weights for the inpatient setting. Such a methodology would provide an improvement over the proposed HSRVcc methodology in that it would produce estimated costs that would better reflect the variation in costs across hospitals and procedures. At least two modifications are needed in the outpatient methodology. First, as discussed below, CMS must adjust for charge compression. Second, the weight calculation methodology needs to account and adjust appropriately for known biases in the Medicare cost report that lead to over-estimation of hospitals' routine costs and under-estimation of ancillary costs. Further research may be needed on the magnitude

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[10] Medicare Payment Advisory Commission, *Meeting Brief: Study of Hospital Charge-Setting Practices*, September 9-10, 2004. Source: http://www.medpac.gov/public_meetings/index.cfm?meeting_id=106, GAO Highlights of GAO-04-772, "Information Needed to Assess Adequacy of Rate-Setting Methodology for Payments for Hospital Outpatient Services. Source: http://www.gao.gov/highlights/d04772high.pdf. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings. The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003. The Effect of "Charge Compression" on Reimbursement of Medical Devices Under the Medicare Outpatient Perspective Payment System: Preliminary Findings, The Moran Company, April 2003. Hospital Charges and Medicare Payments for Implanted Permanent Pacemakers and Implanted Cardioverter Defibrillators, The Lewin Group, April 2003.

[11] C. Hogan, Direct Research LLC., March 2005

of this bias and options to correct for it. The recommended 1-year delay allows time for this additional work.

Although evidence of the effect of charge compression is not new, research that could support an adjustment to offset charge compression was not available. Research just completed now presents a solution. It takes advantage of the detailed coding of supplies charges by revenue center on Medicare claims data to split the single cost-report CCR into separate CCRs for each supplies sub-category. Five supplies sub-categories are used: general supplies, implantables, sterile supplies, pacemakers (and defibrillators), and all other supplies. The division is based on a strong statistical association between the mix of supplies charges (by revenue center) in a hospital and the overall supplies CCR in a hospital. By pooling the information from all hospitals, research using regression analysis was able to develop one set of CCR adjustments reflecting national average CCRs for each of the five supplies sub-categories. Next, the research applied this national-average set of adjustments to each hospital (combining the adjustments with each hospital's actual supplies CCR), and inserted a "decompressed" estimate of cost on each MedPAR record.

The research found a strong and statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's overall average CCR for supplies. Hospitals with a higher share of charges in the pacemaker and implantable device revenue centers (0275, 0278) have higher supplies CCRs. CMS could use the coefficients from a regression model such as this to develop a data-driven adjustment for creating CCRs for sub-categories of supplies. Using the available MedPAR data, only four of the supplies sub-categories have enough charges, on average, to allow such a statistical estimate. The research found, on net after all budget-neutrality adjustments, the average CCRs for the supplies sub-categories which are shown in the table below. The average CCR for all supplies together was 0.33 (top line), but the regression analysis showed substantial variation in CCR by category. The pacemaker category (which also includes hospital charges for a significant portion of defibrillators) has an estimated CCR of 0.46 (or just slightly more than a 100% average markup). The category of general supplies, by contrast, has an estimated CCR of 0.24 (or just over a 300% average markup).

Estimated CCRs for Supplies Sub-Categories	
Supplies subcategory	Net average CCR after budget-neutrality adjustment
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43

0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29
Source: Direct Research, Ltd. analysis of 2004 5% standard analytic file and hospital cost report data. May 2006.	

The research showed that this variation in CCRs across sub-categories has a significant impact on some DRG weights. Cost-based DRG weights would increase for DRGs with substantial charges in the implantable devices and pacemaker/defibrillator revenue centers.

St. Jude Medical strongly believes that any change toward cost-based weights, whether accompanied by the hospital relative value methodology or not, must address the distortion caused by charge compression. The recently completed research demonstrates that such an adjustment is possible and provides a solid analytical basis for a specific adjustment.

More information is provided in the attached presentations to CMS: "Addressing Charge Compression for Implantable Devices" (June 7, 2006) and "Charge Compression for Implantable Devices: Does it exist?" (May 9, 2006). An Executive Summary by Christopher Hogan, Direct Research, LLC , on "A Proposed Solution for Charge Compression" is also attached.

5. SEVERITY-ADJUSTED DRGs (*"DRGs: Severity of Illness"*)

CMS solicited comments on a consolidated, severity-based DRG system (CS-DRGs) in the Proposed Rule. The CS-DRGs are similar, though not identical, to the All Patient Refined DRGs (APR-DRGs). CMS stated in the Proposed Rule that it was seeking comments on the CS-DRGs as well as alternatives that could be used to capture DRG severity and complexity. CMS also requested comments on a time frame for implementation (FY 2007 or FY 2008) of a severity-based DRG system.

St. Jude Medical's ability to conduct modeling on the impact of the proposed CS-DRGs was hampered by the fact that there was only limited information available from CMS at the time the Proposed Rule was released. As noted above, CMS did not provide the necessary Grouper software to analyze the CS-DRG impacts.

In its specialty hospital recommendations last year, MedPAC recommended the use of severity-based DRGs in conjunction with hospital specific weights and cost-based weights. MedPAC examined APR-DRGs and recommended that CMS implement a

severity-based DRG system, similar to APR-DRGs, but did not recommend that APR-DRGs be used.

In the Proposed Rule, CMS noted that implementation of APR-DRGs without modification caused several concerns, including the volatility of rates for low-volume procedures and the potential incentives for more thorough coding of severity due to financial incentives provided by severity-based DRGs.

St. Jude Medical believes that CMS should not implement CS-DRGs or any severity-based DRG system in FY 2007. We support a DRG classification methodology that accounts for patient severity of illness, complexity and patient benefit. These DRG refinements would make allowances for specific DRG assignments that have been previously approved through notice and comment rulemaking. St. Jude Medical recommends that CMS start with the current DRG system and provide overlays for severity, complexity and patient benefit.

CMS notes in the Proposed Rule that the CS-DRGs do not capture complexity of treatment, but provides no suggested mechanism for doing so in the future. We would like to work with CMS in ensuring that any DRG system that will be used by the agency will fully recognize complexity and patient benefit. St. Jude Medical believes that it is <u>essential</u> for any DRG refinements to fully acknowledge these factors.

AdvaMed conducted extensive modeling of one version of severity-based DRGs after MedPAC made its recommendations last year and in November, 2005, shared with CMS a number of potential concerns with moving to severity-based DRGs. Included in those concerns were the failure of the severity-based DRGs to recognize newer technologies with an appropriate payment weight and associated payment level. Our analysis of the proposed CS-DRGs reveals that concern still needs to be addressed. The following examples illustrate several problems with the proposed CS-DRG that call into question the readiness of the proposed severity-based DRG system that fails to recognize such important categorizations.

Improper Classification Under CS-DRGs. Our analysis has revealed that the movement from the current system to CS-DRGs places procedures into inappropriate categories. These mis-categorizations fail to accurately describe the procedure itself, the technology being used, or the resources, complexity or patient benefit of the procedure. Examples are as follows:

- **Current DRGs 118, 551** – In 1997, CMS moved ICD lead and ICD generator/replacement to the pacemaker system with AMI, HF, Shock DRG as justified by average charges (Federal Register, Vol. 62, 45974, August 29, 1997).

Under the CS-DRGs, generator replacement procedures for pacemakers, implantable cardiac defibrillators (ICD), cardiac resynchronization therapy pacemakers (CRT-P) and cardiac resynchronization therapy defibrillators (CRT-D) would be inappropriately categorized together into the same CS-DRGs 243, 244 and 245 (Cardiac pacemaker and defibrillator device replacement with a severity of illness (SOI) levels 1-3) and the ICD lead procedures would map to CS-DRGs 246-248 (Pacemaker & ICD revision). Changing the logic so that ICD generator/replacement map with pacemaker replacements and the ICD lead procedures map with pacemaker and ICD revisions would reverse CMS' 1997 decision without data to justify the change. This, in addition to the fact that there is no variation in the DRGs based upon the type or complexity of the device, would result in a significant penalty to hospitals that treat patients needing implantable defibrillators, which are more complex and resource intensive than pacemakers.

- **Current DRGs 518, 555, 556, 557, & 558** – All of these DRGs would group to CS-DRGs for Percutaneous Cardiovascular Procedures both with and without acute myocardial infarction (CS-DRGs 237-242). DRGs 557 and 558 include drug-eluting stents, and would be placed inappropriately into the same category with bare metal stents.

- **Current DRGs 471, 544 & 545** – These DRGs for either bilateral or major joint replacement procedures, group to CS-DRGs 414 – 419, which are solely for either hip joint or knee joint replacement. The CS-DRGs thus fail to differentiate between single replacement procedures and bilateral revisions, which are more resource intensive and complex. The only distinction made by the CS-DRGs is the distinction based on whether the procedure is performed on a hip or on a knee.

- **Current DRG 496 (combined anterior/posterior spinal fusion)** – Based on the CS-DRG descriptions, it does not appear that there is an appropriate CS-DRG crosswalk from current DRG 496. The effect is that combined anterior/posterior spinal fusion procedures, which require two separate incisions and turning the patient over during surgery, get regrouped with all other spinal fusions. This inappropriate categorization ignores the resource intensive nature and greater length of stay associated with this procedure, and is also contrary to CMS policy dating back to the FY 1998 Final PPS Rule.

- **Current DRGs 110 and 111** – Endovascular aneurysm repair (EVAR), a new generation of surgical services, will experience payment reduction in excess of 12% due to the proposed shift of EVAR into proposed CS-DRGs 234 – 236.

EVAR for treatment of Abdominal Aortic Aneurysms (EVAR-AAA) was first approved in late 1999. EVAR for treatment of Thoracic Aortic Aneurysm (EVAR-TAA) was approved in early 2005. The benefits that this technology offers to patients were reinforced by the implementation of a new "Welcome to Medicare" screening benefit for AAA, enacted under the Deficit Reduction Act of 2005, with implementation effective January 1, 2007, and an award of "New Technology" status for EVAR-TAA in FY 2006. EVAR reduces hospital stays, risk of complications and risk of death resulting from surgery, and is an alternative for many patients where limited or no suitable options were previously available.

Classification of EVAR into CS-DRGs 234 – 236 is inappropriate, and ignores the patient benefit and complexity of these procedures. The CS-DRGs 234 – 236 "Other Vascular Procedures" primarily contain surgeries for peripheral arterial disease – primarily PTA (w, w/o stent) and surgical bypass of the lower limb. This is an inappropriate classification for EVAR that does not recognize the significant clinical and resource differences (i.e. "complexity") inherent in the treatment of aortic and thoracic aneurysms versus peripheral disease. The disparity of net resource consumption for EVAR versus other procedures in the classification is large, yet would not be recognized under CS-DRG reclassification.

Difficult to Obtain a High Severity Level Absent Adverse Patient Consequences. Our analysis has also identified concerns regarding the fact that patients may need to suffer adverse consequences in order for the case to be assigned to a higher severity level. While in certain cases this may appropriately reflect the greater use of resources, our analysis uncovered that in some cases it was impossible to obtain a higher severity level unless the patient had a life-threatening complication. We believe that the severity grouping should reflect complexity and patient benefit as well, and should allow for an increased severity/complexity level even without adverse patient consequences. Our examination of this issue led us to review a number of related procedures for arterial repair or occlusion as follows:

- **DRGs 014, 110, 533, 534, 553, 554, and 559** – When these procedures are mapped to the proposed CS-DRGs, most take enormous reductions because virtually none of the procedures map to either of the two highest severity levels. In order to reach the highest severity levels, the patient must have a number of comorbidities that are unrelated to the basic nature of the procedure, such as a severe infection or renal failure.

CS-DRGs Fail to Adequately Recognize Patient Benefit. Our analysis revealed that CS-DRGs appear to be markedly inadequate to recognize patient benefit. One example that demonstrates this deficiency occurs in the context of the use of a more expensive,

but longer lasting medical device, such as a hip with hard-bearing or other novel surfaces, that may be dictated by a beneficiary's greater health, activity level and greater potential utility over the individual's lifespan. A subset of today's Medicare patients who undergo total joint replacement are very active and have life expectancy rates that may challenge some of the older implant designs. Implant longevity has been the focus of significant clinical study and development for this sector of the medical technology industry. Additionally, implant fixation and range of motion requirements are much more demanding for these patients. Some providers are working to identify patients that are most appropriate to receive these implants based upon such things as family history, overall health and activity level. Unfortunately, the tendency toward better health and higher activity level of these patients would work against them receiving an implant that would be better tailored to their needs, because under the CS-DRGs, such patients would be categorized into the lower level severity. We believe the severity adjustment is flawed because it does not capture resource utilization or the utility of technologies that would be more appropriate for beneficiaries who are more active, healthier, and require a greater range of motion.

Reversal of Recent DRG Refinements. St. Jude Medical's analysis has revealed that the CS-DRGs, if implemented in FY 2007, would arbitrarily eliminate several important changes to DRGs deemed necessary to encourage promising new technologies. This is illustrated by the following examples:

- **Current DRGs 551-552** – In FY 2006, CMS introduced new severity classifications for a number of cardiovascular DRGs based on the presence major cardiovascular conditions (MCV). CMS stated: "Using the MCV list, we tested our assumption that these conditions described a more severe set of cardiovascular surgery patients. We grouped all the cardiovascular surgery patients within MDC 5 based on the presence or absence of an MCV condition. We found that this split was predictive of significantly increased resource use for nine surgical cardiovascular DRGs." Under the proposed CS-DRGs, pacemaker implants would be grouped to CSA-DRGs 228-233 (Permanent Cardiac Pacemaker Implant With & W/O AMI, Heart Failure or Shock), reverting back to classification based on presence or absence of heart failure, AMI, or shock, rather than major cardiovascular condition.

- **Current DRGs 544 and 545** – In last year's Final Rule, CMS eliminated DRG 209 for primary and revision total hip and knee replacement procedures and replaced it with DRGs 544 (primary total hip and knee replacement) and 545 (revisions hip and knee replacement). CMS also created new and updated existing ICD-9 procedure codes to map to DRG 545 for a more accurate description of the various permutations of potential hip and knee revisions. Under CS-DRGs, revision procedures would map to CS 415 (hips) and 418

(knees) with weights reduced approximately 19 to 20%. Relative weights for bilateral total joint replacement, could likewise decline by as much as 40 to 45%. In the FY 2006 rule, CMS noted that

> "we examined data in the FY 2004 MedPAR file on the current hip replacement.... as well as the replacements and revisions of knee replacement.... We found that revisions were significantly more resource intensive than the original hip and knee replacements."

It is difficult to understand how CMS can suggest complete reversal of a categorization in FY 2007 that was not only just implemented in FY 2006, but also supported by CMS with the award of additional ICD-9 procedure codes.

- **Current DRGs 110 and 111** – CMS agreed that endovascular aneurysm repair (EVAR) for treatment of Thoracic Aortic Aneurysm (EVAR-TAA) merited the award of a new technology add-on payment in FY 2006. This technology was also made part of the "Welcome to Medicare" screening benefit under the Deficit Reduction Act of 2005. Implementation of the CS-DRGs would move these procedures inappropriately to CS-DRGs 234-236 (for more general vascular surgeries), serving to nullify or minimize these recent policy decisions recognizing this technology.

- **Current DRGs 557, 558** – CMS agreed, effective after April 1, 2003, to increased payments for drug-eluting stents. These changes, deemed necessary and appropriate by CMS after careful examination and analysis by CMS, would simply be eliminated under movement to CS-DRGs. In 2005, CMS noted that the resource differences between bare metal and drug-eluting stents, stating

  > "We recognize that the resources surrounding bare metal stents and drug-eluting stents differ appreciably and will continue to keep these cases separate..." Federal Reg. Vol. 70, 47294, August 12, 2005.

- **Current DRG 103** – In last year's Final Rule, CMS made a significant coding change to account for the use of an external heart assist devices to recover native heart function. Heart assist devices designed for recovery are increasingly used to treat acute heart failure, thus, avoiding the need for heart transplantation. However, patients with recoverable heart conditions may be as ill and utilize as many hospital resources as a heart transplant patient. CMS recognized the need to accurate reimburse for the use of recovery heart assist devices in the FY 2006 Final Rule, and noted that

> ". . .our data do support that patients having an external heart assist device implanted and removed during the same admission are comparable to in costs and average length of stay to heart transplant and implantable heart assist system patients in DRG 103. . . . we believe that consideration of the comments is best served by recognizing this unique subset of patients, and making a DRG change that acknowledges the increased resources required for improvement in their care. "

The implementation of CS-DRGs would de-couple external heart assist devices from heart transplantation and regroup them with considerably less costly devices. As a result, reimbursement for external heart assist devices would be reduced significantly and the coverage decision made less than one year ago would be nullified. There has been no clinical data or considered policy justification for this change and it is difficult to understand the rationale for CMS to have undone their carefully crafted analysis in less than one year.

We are against the elimination of carefully considered DRG reclassifications, performed with stakeholder input and/or pursuant to notice and comment rulemaking -- some as recently as last year -- that would occur if CS-DRGs were to be implemented. We believe that the CS-DRGs are therefore not ready for implementation in FY 2007, and should not be implemented until the problems noted above are addressed fully. Rather than revisiting past policy decisions, St. Jude Medical believes that CMS should develop and propose a system that establishes severity adjustments for the current DRGs (after eliminating the current CC/no-CC splits), including all of those DRGs that reflect complexity of treatment for some patients. We note that CMS indicated in the Proposed Rule that "a method of recognizing technologies that represent increased complexity, but not necessarily greater severity of illness, should be included in the system." A good first step would be to continue to recognize those technologies that have already been deemed to be worthy of additional consideration under the DRG system.

St. Jude Medical believes CMS should devote significant additional study to the implementation of any refined or revised DRG system, and seeks opportunities to work with CMS in making revisions to the current DRG system to ensure appropriate recognition for severity, complexity and patient benefit.

6. DRG RECLASSIFICATIONS

"DRGs: Carotid Artery Stents"

We disagree with CMS's proposal to keep the current DRG assignments for carotid artery stents, as this step would not adequately reflect the resources consumed in the

procedures. We urge CMS to create a new DRG or pair of DRGs for carotid artery stenting effective FY 2007. Alternatively, as an interim solution, we urge CMS to assign all carotid artery stenting cases to DRG 533 for FY 2007, pending further analysis of MedPAR data and the possible future implementation of severity-adjusted DRGs.

"DRGs: Neurostimulators"

We oppose CMS' recommendation to keep implantation of dual array implantable neurostimulators for deep brain stimulation in DRG 1 (Craniotomy Age >17 with CC) and DRG 2 (Craniotomy Age >17 without CC). We strongly encourage CMS to reclassify these procedures to the more appropriate DRG 543.

"DRGs: Epicardial Leads"

We agree with the proposal to add code 37.74 (Insertion or replacement of epicardial lead [electrode] into atrium) to the DRG logic to capture epicardial leads inserted with CRT-D defibrillators so that all types of defibrillator devices and lead combinations would be included in the following DRGs:

- DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheterization);
- DRG 535 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock); and
- DRG 536 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock).

St. Jude Medical supports movement toward improved accuracy under the inpatient prospective payment system (IPPS) so that patients continue to have access to advanced medical technologies. We look forward to working with you and your staff to address the issues discussed in this letter. Please contact us directly if you have any questions or concerns. We thank you for the opportunity to provide comments, and look forward to continuing to work with you on these important issues.

Sincerely,

Susan Walker

Senior Director, Health Policy and Reimbursement

Attachment 193

ISSUES IN THE USE OF MEDICARE COST REPORTS TO CALCULATE DRG RELATIVE WEIGHTS

June 5, 2006

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1. INTRODUCTION

On April 13, 2006, the Centers for Medicare and Medicaid Services (CMS) published proposed regulations that described significant modifications to the Medicare Inpatient Prospective Payment System (IPPS). Since the introduction of the IPPS, relative weights for the system's Diagnostic Related Groups (DRGs) have been based on hospital charges. The proposed regulations describe CMS' intention to use cost-based relative weights to replace the charge-based approach. Use of cost-based weights will have a significant impact on payments for certain DRGs and, as a result, will have a substantial effect on hospitals.

The impact of the change to cost-based weights on payments to hospitals is the subject of other reports. In general, the use of cost-based weights will result in compression of relative weights, i.e., there will be less difference among weights across DRG categories. More specifically, the relative weights for relatively complex DRGs (especially surgical DRGs) will decline and the relative weights for less complex DRGs (especially medical DRGs) may increase. Although the impact of the changes is discussed elsewhere, some of the key reasons for the changes are discussed in this report.

CMS' cost-based weights are calculated by applying cost to charge ratios reported in hospital Medicare Cost Reports to charges for specific cases. The approach assumes that the cost data in the Medicare Cost Report is an accurate representation of the costs of individual cases. This issue and other related issues are examined in this report. The report includes discussions that address CMS' approach to calculating cost-based weights, the history and purpose of the Medicare Cost Report, problems in the use of the Medicare Cost Report to calculate DRG relative weights, specific findings on the impact of CMS proposed cost-based weights on a set of key cardiac DRGs and recommendations for improving the Medicare Cost Report so that it can be used to calculate relative weights that are more accurate.

2. THE CMS APPROACH TO CALCULATING COST-BASED RELATIVE WEIGHTS

The approach used to calculate departmental costs in the Medicare hospital cost report is at the heart of the CMS approach to calculating cost-based DRG relative weights. The costs calculated in the cost report are used to calculate cost to charge ratios (CCRs), which, in turn, are applied to claims data to support the calculation of a relative weight for each DRG.

CMS, acting upon MedPAC's recommendation, created a methodology to calculate a cost-based hospital specific relative-value (HSRV) that is less complex than that created

by MedPAC. The CMS method involves developing hospital-specific charge-based relative weights at the cost center level to remove the bias introduced by hospital characteristics, such as teaching, disproportionate share, location and size. These weights are then scaled to a facility's costs using national cost center cost to charge ratios, which CMS develops using cost report data. CMS identified ten cost center categories to be used in this calculation. These categories include eight ancillary cost groups plus routine care costs and intensive care costs. The categories were created to properly segment data without overly representing any one area; therefore each category represents at least five percent of charges in the claims data. CMS then uses these cost center groupings to create national average CCRs; these estimated costs are used to develop cost-based relative weights. A more detailed description of this process follows.

Step One: *Cleaning the Data*

CMS grouped all claims using Version 23.0 of the CMS DRGs. Hospitals without cost report data had their claims excluded from the analysis. Similarly, claims with a length of stay less than or equal to zero, as well as those with total charges differing greatly from the sum of their charges for major cost centers were eliminated. Finally, all statistical outliers beyond 3.0 standard deviations from the mean were excluded.

Step Two: *Compute HSRVs for Each Cost Center for Each DRG*

Average charges were calculated for each provider for each of the ten identified cost centers by summing charges in each cost center and dividing by the transfer-adjusted count for each provider. By claim, each cost center's charges were divided by the provider's average charge for the matching cost center across all services to calculate relative charges. CMS then adjusted these charge weights by the provider's CMI. Both relative charges and transfer adjusted case counts were summed by DRG. CMS then determined the average cost by DRG by dividing these summed relative charges by the summed transfer-adjusted case count.

Using MedPAR data, a national average charge for each cost center was calculated by dividing the sum of relative CMI-adjusted charges by the total transfer-adjusted case count. This allowed for "cost center DRG weights" to be created by dividing national average charge for each DRG for each cost center by the national average charge for that cost center. This produced ten weights for each DRG that could be assigned to each claim in turn producing a new CMI for each provider. CMS applied iterations of analysis to this CMI to ensure the national average CMI did not fluctuate.

Step Three: *Compute CCRs from the Cost Reports for Each of the Ten Cost Center Groups Identified*

CMS worked to remove markup differences that exist in certain cost centers by developing national cost center CCRs. A similar analysis as described in Step One applies to their creation of these CCRs. In the end, a geometric mean CCR was determined for each cost center group.

Step Four: *Sum the Average Charge for Each Cost Center from the MedPAR Data and Apply the National CCRs from the MedPAR Files*

Using the national average CCRs from Step Three and total unadjusted charges for matching cost centers in the MedPAR file, CMS determined an estimated cost for each claim. These costs were then summed to produce the total cost for all cases across the nation. The center's overall costs were divided by total costs to calculate a scaling factor for each cost center.

Step Five: *Adjust Relative Weights from Step Two to Cost by Applying Scaling Factors from Step Four*

The scaling factors from Step Four multiplied by the cost center weights from Step Two produce a single final weight for each DRG.

Step Six: *Normalize the Weights*

To accurately compare the results from Step Five with the charge-based weights in effect during FY 2005, each DRG weight must be normalized using the normalization factor of 1.47462. This is the factor applied to FY 2006 charge-based weights to ensure that total payments under IPPS neither increase nor decrease.

To a considerable extent, the accuracy of cost-based relative weights depends on the accuracy of the costs in the Medicare hospital cost report. The cost report, however, was not designed to measure case-specific costs. Instead, as discussed in the next two sections, it was designed to measure a hospital's aggregate allowable cost as defined by Medicare regulations.

3. HISTORY AND PURPOSE OF THE MEDICARE HOSPITAL COST REPORT

As discussed subsequently, the Medicare hospital cost report is an inadequate tool for the calculation of DRG payments. The cost report was developed to support the cost reimbursement approach that was established when the Medicare program was enacted in 1967. Medicare's enabling legislation required the program to pay hospitals for the cost of caring for Medicare patients. Cost reimbursement had been used for some time by several Blue Cross plans prior to the passage of Medicare. The approach adopted for the Medicare program was based on the Blue Cross approach, which required hospitals to prepare and submit annual reports on their costs. The reports were designed to determine the total annual reimbursement due to a hospital for serving a plan's subscribers. Hospitals were paid interim amounts based on an estimate of the total

annual amount to be paid and a retrospective settlement was completed after the cost report was submitted and audited.

The Medicare program adopted the Blue Cross approach, but modified it to reflect the difference between its definition of allowable cost and the Blue Cross definition of allowable cost. The Medicare definition was based on the definition outlined in legislation and regulations while the Blue Cross definition was based on plans' contracts with hospitals.

Despite the differences in definitions of allowable cost, the concepts underlying hospital cost reports were identical for Blue Cross and Medicare. In general, determination of the amount to be paid by a payer using cost reimbursement was based on the following principles:

- Total hospital costs were reported based on the accounting records of the hospital, prior to any adjustments in the definition of allowable costs. These costs are presented in the form of the hospital's final trial balance which is completed to support the preparation of financial statements. The trial balance is the final balance in each of the hospital's general ledger accounts at the end of the fiscal year.
- Adjustments to the trial balance based on the definition of allowable costs are identified. For example, Medicare has never paid for certain costs, such as marketing costs, bad debts and the costs of certain professionals who are paid independently by the program.
- The adjusted trial balance was used to determine costs for each cost center. This determination requires two steps: assignment of direct costs to cost centers and the allocation of indirect costs to revenue centers. When these two steps are completed, an estimate of the total costs associated with each revenue center was calculated.
- Total costs associated with each revenue center were then compared to total charges for that revenue center to arrive at a cost to charge ratio. This ratio measures the relationship between costs and charges for each revenue center.
- Cost to charge ratios were then applied to charges for the payer's patients and an estimate of the cost of caring for those patients was calculated.
- Other costs, such as the costs of indirect medical education, were added to the costs determined by applying cost to charge ratios. Additional reporting requirements were added (financial statements), but the key elements of determining reimbursement are identified in the steps that have been listed.

The costs paid by the Medicare program under cost reimbursement are aggregate estimates that are derived by using the principles that have been described. The

accuracy of the cost determination conventions used in the cost report was assumed. The Medicare program believed that its cost report approach provided a sufficiently accurate measure of aggregate costs incurred by each hospital in serving Medicare patients. The program did not use cost report data to calculate the costs associated with serving specific patients.

As discussed in subsequent sections, an understanding of the methods used in the cost report to calculate aggregate costs is critical to understanding the limitations of the approach when it is used to calculate DRG relative weights.

4. PROBLEMS IN THE USE OF THE MEDICARE COST REPORT TO CALCULATE DRG RELATIVE WEIGHTS

As noted previously, the accuracy of the Medicare program's DRG relative weights depends on the accuracy of the costs reported in the Medicare cost report. The cost report, however, is not a useful source for the calculation of costs in today's hospital payment environment. The limitations of the Medicare cost report as a cost determination tool are well documented in the literature. In an article published in the *Healthcare Management Review*, Magnus and Smith identified several studies conducted over the past two decades that document a variety of issues and shortcomings related to the MCR and its use in health policy decisions[1], including:

- The Prospective Payment Assessment Commission (ProPAC), which was succeeded by the Medicare Payment Advisory Commission (MedPAC), found that the Medicare hospital cost report does not recognize a broad range of indirect costs of providing patient care, even though widely accepted accounting methods would include these expenses. These expenses include the costs of charity care and bad debts, malpractice insurance, growth in working capital and related interest expense, marketing and recruitment costs, investments in cost-saving initiatives, costs for the preparation of the cost report, and patient amenities such as telephones and access to television.
- ProPAC also found that the cost report arbitrarily limits the compensation of hospital-based clinicians, and does not encourage the most accurate method of cost finding.
- Cleverley, in a study of voluntary versus investor-owned hospitals, found that hospitals have had incentives over the years to prepare cost reports to enhance Medicare reimbursement and may have shifted costs by reassigning debt, expenses, and assets among the individual hospitals that comprise multi-hospital systems.

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[1] Magnus SA and Smith DG. "Better Medicare Cost Report Data are Needed to Help Hospitals Benchmark Costs and Performance." *Healthcare Management Review*, Vol. 25., No. 4, Fall 2000.

- Johnsson and colleagues found that individual hospital cost reports tend to overstate costs and to minimize profitability in order to maximize cost recovery. In addition, Medicare guidelines allow for a wide range of acceptable cost accounting practices, which makes it difficult to compare costs across hospitals as well as individual departments within hospitals.
- Ashby and other ProPAC staff found evidence of sophisticated cost shifting among hospitals that may be difficult to detect in the cost report. In the same study, Ashby and colleagues also found that some of the cost report's cost-finding methodologies are inaccurate, which causes variation in the validity of specific DRG costs. Ashby also observed that while total Medicare inpatient costs in the cost report are reasonably reliable, when separated into routine inpatient and ancillary costs, they become less reliable, and that cost report data should not be used for measuring micro-level costs.
- In separate studies, Hwang and Kirby, and Gianfrancesco described how patient days are used to allocate inpatient care costs in the cost report rather than multiple other cost drivers, resulting in distortions in overall costs.

Magnus and Smith contend that the research efforts they reviewed provide evidence that the cost report should be more closely scrutinized as a source of data on the true costs of individual hospitals and that certain conclusions drawn solely from data contained in cost reports should be viewed "skeptically."[2]

In another study by Magnus and Kane, the authors found that many cost report measures of cost, including operating and nonoperating expenses, are not consistently defined or separated. For example, the authors found that one hospital in the study recorded a $5 million onetime payment to its medical school as an operating expense in its cost report but as a nonoperating expense in its audited financial statements, resulting in a two percent discrepancy in the hospital's operating margin. The researchers cite several other deficiencies in the cost report, including issues regarding the accurate reporting of revenues and expenses. They conclude that the "financial accounting elements in the Medicare cost report are unreliable, poorly defined and lacking in critical detail" and that "Medicare cost report financial data give only a limited and often inaccurate picture of the financial position of hospitals."[3]

A study conducted by the Rural Policy Research Institute (RUPRI) Center for Rural Health Policy Analysis found differences in the information in Medicare cost reports and audited financial statements among hospitals. The study included comparisons of fourteen financial ratios for rural non-critical access hospitals as reported in the hospitals' cost reports and audited financial statements. For forty percent of hospitals in the study, researchers found that total hospital margin differed by more than five

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[2] Ibid.

[3] Kane NM and Magnus SA. "The Medicare Cost Report and the Limits of Hospital Accountability: Improving Financial Accounting Data." *Journal of Health Politics, Policy and Law*, Vol. 26, No. 1, February 2001.

percent between cost reports and audited financial statements. The researchers concluded that because of these differences, Medicare cost reports should not be used as a single source of data for assessing the financial performance of rural hospitals.[4]

Limitations of the cost report were also documented in studies conducted by Miller for the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (OASPE) and for ProPAC.[5] These studies focused on the variation in methods used by hospitals to assign direct costs and allocate indirect costs to revenue centers. The studies found that differences in accounting among hospitals provided considerable opportunity for variances in reporting to occur. In the 1983 OASPE study, assignment of direct costs and allocation of indirect costs were measured prior to the implementation of the IPPS. During the period of this study, hospitals had incentives to report higher inpatient costs because Medicare was the primary payer using the Medicare cost report for cost reimbursement and the Medicare program paid a considerably higher portion of inpatient costs than outpatient costs. Study findings indicated that hospitals used cost assignment and allocation methods to respond effectively to this incentive. In the 1989 OASPE study, assignment of direct costs and allocation of indirect costs were studied in the same hospitals, five years after the introduction of the IPPS. During the period of this study, the Medicare program no longer used cost reimbursement to pay hospitals for inpatient services, but retained its use to pay for outpatient services provided to Medicare patients. Study findings indicated that hospitals that had used cost assignment and allocation methods to increase inpatient payment in 1982 were able to use similar principles to increase outpatient payments. The findings also indicated that the ability of hospitals to manipulate costs reported in the cost report implied that there was sufficient variance in the measurement of cost to question the accuracy of the costs of individual cost centers.

The ProPAC study completed by Miller in 1992 addressed the accuracy of departmental costs reported in the cost report more directly. In this study, DRG-specific costs calculated by more than thirty hospitals that used sophisticated cost accounting systems for internal reporting were compared to DRG-specific costs derived using Medicare cost reporting principles for the same hospitals. The cost accounting systems used standard costing based on management engineering studies conducted to determine the precise inputs used in specific services and the costs of those inputs. Study findings identified substantial variances between costs calculated by hospital cost accounting systems and costs calculated using Medicare cost reports which led to the conclusion that the Medicare cost report did not necessarily provide accurate measures of cost, especially when it was used to calculate the costs of specific services.

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[4] Chen L, et.al. "An Analysis of the Agreement of Financial Data Between the Medicare Cost Report and the Audited Hospital Financial Statement." *Rural Policy Brief*, Vol. 9, No. 4, May 2004.

[5] Miller, H.. *Evaluation of Methodologies to Measure Hospital-Based Ambulatory Care Costs*, (Center for Health Policy Studies, Columbia, MD, 1983); *Replication of 1982 Study of Resource Use Costs in 25 Hospitals*, (Center for Health Policy Studies, 1989) and *Evaluation of the Use of Medicare Cost Reports as a Research and Policy Analysis Tool*, (Center for Health Policy Studies, 1992).

Although the literature has identified limitations in the accuracy of Medicare cost reports when they are used for purposes other than the determination of Medicare allowable cost, it is important to understand the underlying causes of these limitations. Inaccuracies in the determinations of departmental or service-specific costs in cost report data are caused by a lack of uniformity in the accounting and allocation principles used by hospitals. In addition, cost reporting principles calculate aggregate costs at the departmental level without regard for the differences in hospital charge setting practices within cost centers. Both of these issues are discussed in the paragraphs that follow.

The steps used in the Medicare cost report to calculate revenue center cost to charge ratios were outlined in Section 3 of this report. Each step provides opportunities to introduce inaccuracies in calculations. In summary, these steps are:

- Total hospital costs are reported in worksheet A, based on the accounting records of the hospital, prior to any adjustments in the definition of allowable costs. These costs are presented in the form of the hospital's final trial balance.
- Adjustments to the trial balance based on the definition of allowable costs are identified in supplements to worksheet A.
- The adjusted trial balance is used to determine each cost center's costs. This determination requires two steps: assignment of direct costs to cost centers and the allocation of indirect costs to revenue centers.
- Total costs associated with each revenue center are compared to total charges for that revenue center to arrive at a cost to charge ratio.

Accounting is far less precise than is generally assumed by non-accountants. Accountants use their judgment to classify assets, liabilities, revenues and costs. This judgment must be applied in the context of Generally Accepted Accounting Principles (GAAP), but GAAP allows for considerable variation in the recording of accounting information. The cost report focuses on the classification of costs. Worksheet A is the product of a year long effort by a hospital's accounting staff to identify and classify costs as they occur. In most instances, costs are readily classified, such as salaries paid to nurses. In some instances, however, judgment must be applied. For example, if a hospital incurs costs to repair its facility, the costs are normally recorded as "Repairs and Maintenance Expense", the term that is typically used for the related expense account in the hospital's general ledger. If the repairs are extensive and intended to improve the facility for more than one year, they may be treated as an addition to assets rather than as an expense. If a portion of the expenditure will have a long-term effect and another portion is for routine repairs, the amount of the expenditure may be split between the asset and the expense account. Although there are rules governing the amortization of assets and other rules that require minimum standards for capitalizing the value of repairs, the decision on how to treat such an expenditure is based on the management's

judgment. Different people faced with the same set of facts may reach different conclusions, based on their perceptions. As a result, there is far less uniformity in the definitions used to prepare the trial balance than may be assumed.

The variations that are inherent in the trial balance are the initial point at which departmental and service-specific costs may be distorted. The adjustments to the trial balance that are made in the cost report to eliminate costs that are not allowed by the Medicare program can have a far greater impact. As was noted in the review of the cost report literature, costs such as marketing, recruiting, charity care, bad debts and malpractice insurance are removed from the account balances in the trial balance because they are not allowed by the Medicare program although they are real costs incurred by hospitals and are included in hospitals' financial statements.

The distribution of the adjusted trial balance's costs to cost centers, which is completed in Worksheet B, is a significant limitation of the cost report when it is used to determine other than aggregate hospital costs. Direct costs are assigned to cost centers based on how they are recorded during the year. The rules for assigning costs vary by hospital and by activity. For example, although it seems obvious that salary costs of nurses engaged in routine inpatient care will be assigned to routine care, variations in such assignments occur frequently. If a nurse spends a portion of his or her time in routine care and a portion in the ICU, salaries should be allocated proportionately. Nevertheless, many hospitals do not track such movement among nurses and will assign all of the costs to the revenue center that is designated for the nurse. Although a portion of the nurse's time should be charged to the ICU, it is highly likely that all of the nurse's salary will be charged to routine care. Problems in cost assignment are pervasive. If one hospital has a single cost center for housekeeping, it will record all relevant costs in that cost center and then allocate them as part of the cost allocation process. If, however, a hospital decentralizes housekeeping services, costs associated with housekeeping for a specific department may be treated as direct costs for that department. Similarly, some hospitals allow departments to purchase medical supplies, while all other supplies are purchased centrally. Depending on the hospital's accounting system, the supplies purchased by departments may be recorded as a direct expense of the department or as part of the cost of Central Supplies, which is allocated across departments. In the OASPE studies conducted by Miller, there was considerable variation in the approaches used by hospitals to assign costs to departments.[6]

Worksheet C is used to allocate indirect costs to revenue centers. Indirect costs are incurred by all cost centers for which hospitals do not set charges. Indirect cost centers include housekeeping, maintenance, utilities, administration and several other areas of hospital activity. These costs are allocated to revenue centers based on a variety of formulae that are intended to provide the most accurate distribution of costs. Despite

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[6] See Miller, op.cit.

this intent, there are variations in the methods used by hospitals. In fact, there are cost centers for which there is no precise way to determine which allocation basis should be used. Some allocation bases are obvious, such as the allocation of utilities costs based on the square feet occupied by revenue centers. Allocation of administrative costs is far less obvious and as a result, hospitals can use different allocation bases to distribute administrative costs, including number of FTE personnel in each revenue center, total revenue center costs prior to the allocation of administrative costs or total salary costs.

Each of the issues that have been raised contributes to limitations in the use of cost reports to calculate costs of revenue centers. An additional limitation must be considered when cost center data are used to calculate cost to charge ratios and these ratios are applied to the calculation of DRG relative weights. The ratio that is calculated assumes a constant relationship between costs and charges for all costs included in the cost center. For example, application of a cost to charge ratio for supplies to all supplies assumes that a hospital has a common markup for all supplies, although it is clear that markups vary greatly. The impact of this problem is obvious. If it is assumed that a hospital's cost to charge ratio for the Medical Supplies revenue center is 0.25 but the markup for a specific Medical Supplies item is only two times cost for an item that has a charge of $6,000.00 and the item is the only supply item used for the DRG, the cost for Supplies associated with the DRG will be $1,500.00 rather than the actual cost of $3,000.00.

Varying direct cost assignments, use of varying cost allocation bases and the assumption that markups are uniform within a revenue center significantly affect the accuracy of costs per unit of service that are calculated using cost to charge ratios. Although the approach is sufficient to meet the original purpose of the cost report, i.e., calculation of Medicare reimbursable cost, it does not provide accurate data for the calculation of unit costs or for setting DRG weights.

5. COMPARISON OF COSTS CALCULATED USING MEDICARE COST REPORT DATA AND COSTS MEASURED USING HOSPITAL COST ACCOUNTING SYSTEMS

It is critically important to understand the extent of the impact of using the CMS approach to calculating and applying cost to charge ratios in the development of DRG weights. Cost accounting data were collected from a sample of hospitals to investigate this impact. We sought a geographically dispersed hospital sample that included a range of hospitals by size. All hospitals selected were required to be using a cost accounting system that was based on standard costs and not cost to charge ratios. We were especially interested in a specific set of cardiac DRGs and therefore, focused on hospitals that provided those services. Our ability to collect data was significantly limited by the time available to respond to the proposed regulations. The specific DRGs of interest are listed in Appendix A and the hospital sample, which includes 22

hospitals, is identified in Appendix B. The 22 hospitals reported costs for 7,552 cases in the DRGs of interest. Our data collection and analysis approach is presented below. We were especially interested in measuring actual costs for each selected DRG and comparing these costs to the Medicare DRG payment that had been made in the past and that which would be made under the proposed regulations.

Our findings are presented in two primary comparisons; a comparison of the cost per case by DRG based on cost accounting data compared to cost per case calculated using cost-to-charge ratios. The second comparison is an estimate of the profitability by DRG based on comparing Medicare payments for specific DRGs to hospital costs for these DRGs derived from hospital cost accounting systems. In both instances, comparisons were made for the same period, i.e., the cost accounting data was collected for the period that matched hospital fiscal years used for cost reports.

Data Analysis and Preparation

Our data analysis consists of four calculations to prepare information for our comparisons presented in the following section.

Step One: Develop cost per case from cost accounting data. Using the data collected from the cost accounting system at each hospital, actual costs were categorized as: Routine, OR, ICU, Supplies, Drugs, Lab, X-ray and other. Costs were allocated to each of these designations by the cost accounting system's pre-established definitions, which are based on revenue codes. Each hospital also provided the total cost and number of cases for each DRG, which allowed for the cost per case to be calculated.

Step Two: Develop cost-to-charge ratios. We calculated cost to charge ratios using the most recent Medicare Cost Report data for each facility from the Healthcare Cost Reporting Information System (HCRIS). We used HCRIS data to obtain costs and charges by revenue center and by facility. These revenue center costs and charges were combined into broader categories as defined below:

Category	Revenue Center
Drugs	Intravenous Therapy; Drugs Charged to Patients
ICU / CCU	Intensive Care Unit; Coronary Care Unit; Burn Intensive Care Unit; Surgical Intensive Care Unit; Other Special Care Unit (specify)
Lab	Laboratory; Whole Blood & Packed Red Blood Cells; Blood Storing, Processing, & Trans.
OR	Operating Room; Anesthesiology; Recovery Room
Routine	Adults and Pediatrics (General Routine Care); Nursery; Skilled Nursing Facility
Supplies	Medical Supplies Charged to Patients
X-Ray	Radioisotope; Radiology-Diagnostic; Radiology-Therapeutic
Other	Occupational Therapy; ASC (Non-Distinct Part); Renal Dialysis; Electroencephalography; Speech Pathology; Other Ancillary (specify); Delivery Room and Labor Room; Physical Therapy; Respiratory Therapy; Electrocardiology

After combining revenue center costs and charges in appropriate categories, cost-to-charge ratios were calculated by category and by facility.

Step Three: Calculate costs using MEDPAR data. We used the 2004 Medicare Provider Analysis and Review ("MEDPAR") file to obtain inpatient charges by facility, DRG and revenue center. Charges by revenue center were then cross-walked to the appropriate cost report revenue center / category where charges were accumulated by facility, DRG and category. Using the cost-to-charge ratios developed in the first step, cost-to-charge ratios were applied to the accumulated MEDPAR data at the facility and category level to compute facility specific costs by category and DRG.

Step Four: Calculate Medicare payments by DRG. The Medicare DRG payments to each hospital were calculated using the predefined payment formula established by CMS. This equation derives the Prospective Payment System (PPS) Operating Payment and Capital Payment for each facility using IME, DSH and other publicly available factors. Medicare's payments were estimated for 2004 using that year's charge-based relative weights and for 2007 using the new cost-based relative weights.

Findings

As previously noted, we completed two analyses: first, we compared costs based on hospital cost accounting data to costs based on cost to charge ratios, by DRG, for each hospital in our sample. Second, we compared the profitability of each DRG based on comparing actual cost to DRG payments using the 2004 charge-based weights and the cost-based weights as developed by CMS and published in the proposed rule.

Our analyses yielded two major findings. First, we found differences in costs calculated using cost accounting data compared to costs calculated using cost to charge ratios. More importantly, the differences were significant and consistent. Costs calculated using cost to charge ratios were substantially lower than costs reported in hospital cost accounting systems for all six of the cardiac DRGs of interest. The percent difference in costs averaged 28.8 percent. It is apparent that the use of cost to charge ratios to calculate costs consistently and significantly understates costs for DRGs that include implantation of pacemakers and defibrillators. The findings are presented in Table 5.2.

Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk	$ 22,291	$ 16,740	$ 5,551	25%
116 Oth Perm Cardiac Pacemaker Impla	$ 15,438	$ 11,069	$ 4,369	28%
118 Pacemaker Dev Replacement	$ 12,160	$ 8,265	$ 3,895	32%
515 Cardiac Defib Impl W/O Cath	$ 35,511	$ 25,347	$ 10,164	29%
535 Car Defib Impl w Cath AMI	$ 47,089	$ 33,165	$ 13,925	30%
536 Car Defib Implant wo AMI	$ 41,602	$ 29,570	$ 12,032	29%

Second, we calculated profitability for each of the same DRGs by calculating payments based on 2004 charge-based weights and comparing them to 2004 hospital costs, measured using cost accounting data. As can be seen in Table 5.3, hospitals are incurring substantial losses for each of the cardiac DRGs of interest under CMS' current charge-based approach for calculating DRG weights.

When we calculated profitability based on the cost-based weights in the proposed rule, losses on cardiac DRGs increased from an average of 20.0 percent for charge-based weights to an average of 38.2 percent under the proposed cost-based weights. If the intent of the proposed rule is to reflect costs of hospital services in payment amounts, the cost-based DRG weighting methodology falls far short of this intent. The findings are presented in Tables 5.3 and 5.4.

Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk	$ 18,410	$ 22,291	$ (3,881)	-17%
116 Oth Perm Cardiac Pacemaker Impla	$ 12,246	$ 15,438	$ (3,192)	-21%
118 Pacemaker Dev Replacement	$ 8,352	$ 12,160	$ (3,808)	-31%
515 Cardiac Defib Impl W/O Cath	$ 27,703	$ 35,511	$ (7,808)	-22%
535 Car Defib Impl w Cath AMI	$ 41,781	$ 47,089	$ (5,308)	-11%
536 Car Defib Implant wo AMI	$ 32,587	$ 40,163	$ (7,576)	-19%

Cardiac DRGs				
115 Perm Pacemkr Impl W/Ami/Hf/Shk**	$ 13,673	$ 22,291	$ (8,618)	-39%
116 Oth Perm Cardiac Pacemaker Impla**	$ 9,173	$ 15,438	$ (6,265)	-41%
118 Pacemaker Dev Replacement	$ 7,185	$ 12,160	$ (4,975)	-41%
515 Cardiac Defib Impl W/O Cath	$ 21,466	$ 35,511	$ (14,045)	-40%
535 Car Defib Impl w Cath AMI	$ 30,513	$ 47,089	$ (16,576)	-35%
536 Car Defib Implant wo AMI	$ 27,018	$ 40,163	$ (13,145)	-33%

** Several DRGs were reorganized in the proposed rule. Under the proposed rule, cases that were grouped in DRG 115 are grouped in DRG 551; cases that were grouped in DRG 116 are grouped in DRG 552.

The use of cost report data results in substantial inaccuracies in the calculation of costs of specific DRGs. When costs based on cost reports are compared to actual costs measured by hospitals for the DRGs that were studied, differences as great as 41 percent were measured with an average difference of approximately 30 percent. These differences increase losses already incurred by hospitals for many of the DRGs studied. If the proposed cost-based weights are implemented, hospitals will receive as little as 60 percent of their costs for some DRGs.

6. RECOMMENDATIONS TO IMPROVE THE MEDICARE COST REPORT'S VALUE AS A TOOL FOR CALCULATING DRG RELATIVE WEIGHTS

The Medicare cost report was designed to measure aggregate allowable costs, not service-specific costs. Despite its limitations, it is being used by CMS to establish DRG relative weights. As has been discussed, however, its use is likely to result in overpayment for some services and substantial underpayment for others. If cost report data are to be used to establish DRG relative weights, there is a need to modify it to measure the costs that are of interest. Two approaches for improving cost reports should be considered:

- Continued use of the existing cost reporting approach, but with improvements, and
- Design of a supplement to the cost report to be used to set cost-based weights.

Each of these approaches is discussed in the paragraphs that follow.

Improvements in the existing cost reporting approach. Although continued use of the existing cost reporting approach will not provide the most useful information for establishing DRG relative weights, steps can be taken to improve its accuracy and reduce distortions in costs used to set relative weights. Five steps should be considered.

- Prescribe a uniform chart of accounts that converts traditional cost objects to cost centers as part of the accounting process,
- Include all costs, not only allowable costs,
- Require greater uniformity in assigning costs to cost centers,
- Evaluate cost allocation bases and prescribe the use of the most appropriate bases, and
- Expand the number of ancillary cost centers to recognize differences in markups.

The Medicare program has not prescribed a uniform chart of accounts that all hospitals must use, although the account listings identified in Worksheet A have led to the development of a "de facto" chart of accounts that is used by many hospitals. All hospitals use charts of accounts that can support the account listing in Worksheet A. These accounts, however, are based on traditional accounting principles aimed at determining aggregate hospital costs. Rather than identify the costs of operating departments or cost centers, the existing trial balance identifies traditional cost objects, e.g., salaries, fringe benefits, supplies and utilities. The amounts listed in the trial balance for these cost objects represent total expenditures of each type that have been recorded over the course of a year.

Because traditional cost objects are used in hospital accounting systems, it is necessary to take the extra step of assigning each cost element to a cost center. A restructured chart of accounts that incorporates the use of cost centers rather than traditional cost objects would eliminate the extra step of assigning costs to cost centers as part of the cost reporting process. Assignments of cost would still need to be made, but they would be made as part of the ongoing accounting process rather than as an additional cost reporting step. Although there are no assurances that accuracy will be improved, focus on the assignment of costs as part of a hospital's accounting system is likely to lead to increased consistency in cost assignment decisions. Moreover, a change in the chart of accounts that emphasizes cost center accounting is a critical initial step in movement toward more sophisticated cost accounting.

In the cost report, non-allowable costs are removed from a hospital's trial balance to determine total allowable Medicare reimbursement, but these costs should be included in the calculation of DRG relative weights. When CMS uses cost report data to determine relative resource use among DRGs, removal of non-allowable costs distorts the measurement process. It is important for CMS to realize that when it uses cost data to establish DRG relative weights, it is unimportant whether Medicare reimbursement allows or does not allow a specific cost. CMS' objective should be to measure relative resource use across DRGs as accurately as possible and such measurement requires consideration of all costs.

Regardless of whether a new chart of accounts is introduced or existing charts of accounts continue to be used, there is a need to improve consistency in the assignment

of costs to cost centers. Regardless of how hospitals may be organized, they should be required to use similar approaches to assign costs. Standards are needed to determine how nursing and other professional salaries are distributed among cost centers when a staff member spends time working in more than one cost center. Similarly, standards are needed to be certain that there is consistency in how supply and pharmaceutical costs are assigned, i.e., to revenue centers or to Central Supply or Pharmacy. The Medicare program's past reluctance to promulgate standards were tied to the use of the cost report to determine aggregate reimbursable cost. If the cost report is to be used to calculate DRG relative weights, there is a need for increased consistency in the assignment of costs.

In addition to prescribing methods of assigning cost, there is a need to increase consistency in the principles used to allocate indirect costs to revenue centers. As previously discussed, selection of the most accurate allocation base for some revenue centers is straightforward. Utilities costs should be allocated based on square feet occupied by a cost center. Selection of appropriate allocation bases for other revenue centers is more difficult. For example, is it more accurate to allocate administrative costs based on the number of FTEs in a revenue center or on the total costs of the revenue center? It is less important to determine which approach is most accurate than it is to decide on which approach will be used by all hospitals to be certain that there is consistency in the data that are being combined to calculate DRG relative weights.

Increasing the number of revenue centers included in the cost report is the most important step that can be taken to improve the quality of cost report data used to calculate DRG relative weights. In its proposed regulations, CMS chose to combine revenue centers, which exacerbates distortions in cost measures. Some revenue centers have little variation in the markups applied to individual costs that are incurred, e.g., Routine Care, ICU and CCU. On the other hand, other revenue centers, including Diagnostic Radiology, Laboratory, Medical Supplies and Pharmacy, frequently include costs and charges for items for which markups may vary considerably. Since the cost to charge ratio is consistently applied to charges for all items in the revenue center to determine cost-based relative weights, it is highly likely that the costs used for several items will be substantially higher or lower than is appropriate. Although this issue is far less important in the determination of total reimbursable cost, it can be critical in determining the cost of a specific DRG. If the markup for all or most of the supplies used for a specific DRG are higher or lower than the average markup reflected in the cost to charge ratio, the relative weight that is calculated for that DRG may be significantly distorted. Analyses must be completed to determine how and why markups differ among items within a revenue center and additional revenue centers should be created to reflect the variances in markups that occur.

Each of the improvements in the existing cost reporting approach that have been identified will increase the accuracy of DRG relative weights as compared to the

approach that CMS described in the proposed regulations. Significantly greater changes in cost reporting are required, however, if CMS wants to substantially improve the accuracy of the DRG relative weight calculation process.

Design of a supplement to the cost report to be used to set cost-based weights. The purpose of the cost report is changing. The new objective for cost reports is to provide information to support an accurate calculation of the costs of resources required to provide the services described by each DRG. Calculation of allowable costs for Medicare reimbursement may still be perceived as needed by CMS, but must now be considered secondary to the need to calculate accurate DRG relative weights.

CMS needs a new cost report structure to accomplish the level of accuracy in cost measurement that is required. The structure should focus on the costs incurred to provide the services included in each DRG, as is currently available in cost accounting systems that many hospitals are now using. Although such systems were not in widespread use as recently as ten years ago, they are currently used by a large number of hospitals. If such systems are designated as required for cost reporting and small and rural hospitals are unable to purchase them, the Medicare program can pay these hospitals differently, as they do now. (A large number of rural hospitals are designated as critical access hospitals; these hospitals are paid using cost reimbursement).

CMS needs to take three steps to begin to design a supplement to the cost report that focuses on the calculation of DRG weights:

- Focus on what is being measured,
- Require the use of a cost accounting system that measures costs by DRG, and
- Establish minimum requirements for cost accounting systems.

The need to focus on the purpose of measuring costs has been the subject of much of this report. For its proposed move to the use of cost-based DRG weights, CMS has relied on a cost reporting structure designed for other purposes. A more appropriate structure can be developed to assure the fairness of the weights that are established.

As noted, many hospitals are using cost accounting systems that calculate DRG-specific costs. These systems have evolved to the point where their accuracy has been tested and they are regularly used to support management decisions. Although the systems vary to some extent, they are based on the measurement of standard costs, using approaches that are reasonably similar across hospitals. The DRG-specific cost data produced by these systems needs to be the foundation of a new cost report. Steps can be taken to design a report that requires DRG-specific costs to be reconciled to traditional accounting costs, but the use of cost accounting systems will eliminate the need for many of the concerns that have been identified for CMS' proposed method for calculating DRG weights.

CMS can identify requirements for acceptable cost accounting systems as part of the design of a new cost reporting format. Most hospitals will not need to modify their financial accounting systems nor will they be required to change the ways in which they present their financial statements. Instead, they will be able to report to CMS the same data that they use in management decision-making. Most importantly, far more accurate cost data will be available to calculate DRG relative weights.

APPENDICES

Appendix A: DRGs of Interest

DRG	
115	Perm Pacemkr Impl W/Ami/Hf/Shk
116	Oth Perm Cardiac Pacemaker Impla
118	Pacemaker Dev Replacement
515	Cardiac Defib Impl W/O Cath
535	Car Defib Impl w Cath AMI
536	Car Defib Implant wo AMI

Appendix B: Participating Hospitals Valid Data

Hospital	State
Christ Hospital	OH
Depaul Health Center	MO
Florida Hospital	FL
Good Samaritan Hospital	IL
Jewish Hospital	KY
Lahey Clinic Hospital	MA
Lancaster General Hospital	PA
Mease Countryside Hospital	FL
Mease Dunedin Hospital	FL
Morton Plant Hospital	FL
Morton Plant North Bay Hospital	FL
Orlando Regional Medical Center	FL
Providence Everett Medical Center	WA
Santa Rosa Memorial Hospital	CA
St. Anthony Hospital	OK
St. Francis Hospital	IL
St. Joseph's - Kirkwood	MO
St. Joseph's - St.Charles	MO
St. Mary's Hospital	WI
St. Mary's - Jefferson City	MO
St. Mary's - St. Louis	MO
Strong Memorial Hospital	NY

Region*	Participating Hospitals		Number of Cases	
	Count	%	Count	%
1	1	5%	479	6%
2	1	5%	599	8%
3	1	5%	887	12%
4	7	32%	2,982	39%
5	4	18%	1,295	17%
6	1	5%	346	5%
7	5	23%	495	7%
8	0	0%	0	0%
9	1	5%	189	3%
10	1	5%	280	4%
Totals	**22**	**100%**	**7,552**	**100%**

** State location of a hospital was mapped against CMS Regions*

Appendix C2: Geographic Distribution of Cases, By State

	No. of Hospitals	No. of Cases
Region 1		
Connecticut	0	0
Maine	0	0
Massachusetts	1	479
New Hampshire	0	0
Rhode Island	0	0
Vermont	0	0
Region 2		
New Jersey	0	0
New York	1	599
Puerto Rico	0	0
Region 3		
Delaware	0	0
District of Columbia	0	0
Maryland	0	0
Pennsylvania	1	887
Virginia	0	0
West Virginia	0	0
Region 4		
Alabama	0	0
Florida	6	2,468
Georgia	0	0
Kentucky	1	514
Mississippi	0	0
North Carolina	0	0
South Carolina	0	0
Tennessee	0	0
Region 5		
Illinois	2	489
Indiana	0	0
Michigan	0	0
Minnesota	0	0
Ohio	1	392
Wisconsin	1	414
Region 6		
Arkansas	0	0
Louisiana	0	0
New Mexico	0	0
Oklahoma	1	346
Texas	0	0
Region 7		
Iowa	0	0
Kansas	0	0
Missouri	5	495
Nebraska	0	0
Region 8		
Colorado	0	0
Montana	0	0
North Dakota	0	0
South Dakota	0	0
Utah	0	0
Wyoming	0	0
Region 9		
Arizona	0	0
California	1	189
Hawaii	0	0
Nevada	0	0
Region 10		
Alaska	0	0
Idaho	0	0
Oregon	0	0
Washington	1	280

	No. of Hospitals	No. of Cases
Totals	22	7,552

** State location of a hospital was mapped against CMS Regions*

Addressing Charge Compression for Implantable Devices

Medtronic, Johnson & Johnson, Boston Scientific,
and St. Jude Medical meeting with CMS
June 7, 2006

Agenda

- Introductions
- Recap of May 9 meeting on IPPS
- History of industry concerns with charge compression
- Evidence on existence of charge compression
- Potential approach to counterbalance effects of charge compression
- Policy recommendations on IPPS proposed rule

May 9, 2006 Meeting

- Companies raised concerns about:
  - Differences in CMS and MedPAC approach to HSRV and cost-based weights
  - Methodological flaws in CMS HSRVcc proposal
  - Policy concerns and overall accuracy of HSRV and cost-based weights
  - Technical concerns with CMS CS-DRGs
  - Timing of implementation
- Agreed to return with recommendations
  - Charge compression one of many issues that must be addressed
  - Today's recommendations start the work, but industry may identify/recommend additional refinements

Longstanding Concerns with Charge Compression

- Industry has worked with CMS for 6 years on charge compression in OPPS
  - Inaccurate estimates of costs a key barrier to long-term stability in OPPS
    - Payment rates for defibrillators (for example) thousands of dollars off
  - CMS has used external data and payment floors in the past, but no robust solution for the future
- Movement toward cost-based weights in IPPS will expand the problem of charge compression
  - Significant concern about patient access to therapies shown to represent substantial clinical improvement over current alternatives

Evidence on Existence of Charge Compression

- Numerous analyses over the past 6 years
- Today focus on:
  - Benchmarking charge mark-ups found in OPPS to external data on costs (IMS)
  - Evidence of charge compression from Medicare data & potential adjustment

Benchmarking of Charge Mark-Ups Found in OPPS to External Data on Costs

(See attached Moran Company slides)

53

Evidence of Charge Compression from Medicare Data & Potential Adjustment

Charge Compression: Issue

- **The issue: one average CCR for all supplies/devices**
  - Cost report has one line for all supplies/devices
  - Generates one CCR for all supplies/devices pooled
  - But numerous sources say markup is lower (CCR higher) for high-cost devices
  - So estimated cost (charge x average supply/device CCR) understates cost of high-cost devices, overstates routine supplies cost

55

Initial Analysis: Demonstrate Correlation Between CCR & Case Mix

- Use CMS data to show evidence of charge compression
- If - Then
  - If charge compression exists,
  - Then supplies CCR should vary systematically with supplies mix.
- Calculate fraction of cases in DRGs with high supplies charges
  - Three overlapping DRG categories based on national average supplies charges ($30K+, $20K+, $15K+, avg. supplies $ per case)
  - Find fraction of hospital cases in these DRGs
- Regress hospital supplies CCR on control variable and case mix
- Shows correlation and dose/response relationship (next slide)
- Did not translate into a workable policy approach
- Presented here to show that supplies mix affects supplies CCR

Initial Analysis: Hospital CCR as Function of Case Mix

Summary of Three Regressions: Hospital Supplies CCR as Function of % Cases in Supplies-Intensive DRGs		
Casmix Measure: % of cases in DRGs with	**Coefficient on Casemix Measure**	
	Coeff.	t-stat.
30K+ average supplies charge.	1.07	4.05
20K+ average supplies charge	0.62	3.96
15K+ average supplies charge	0.21	4.02
Source: Analysis of FY 2004 MedPAR and FY 2003 cost reports. Regression included constant and term for average hospital CCR excluding supplies.		

LS

Second Attempt: Vary CCR by Supplies Revenue Center Code

- Revenue centers identify charges in key sub-categories:
  - Pacemaker/defibrillator, other implantable device.
  - Versus: general supplies, general sterile supplies
- Create and apply data-driven CCR adjustment for supplies sub-categories.
  - Regress supplies CCR on supplies mix to estimate average CCR variation across supplies sub-categories.
  - Use regression coefficients to adjust hospital supplies CCR.
  - Sub-category CCR = actual hospital supplies CCR + national average regression-based sub-category adjustment.
  - "Decompressed" cost = subcategory charges x sub-category CCRs.
  - Force budget neutrality in each hospital (total supplies cost constant)
  - Re-estimate DRG weights with "decompressed" cost.

Regression Analysis

- Sum hospital supplies chgs. by rev. center (5% SAF).
- Supplies mix: % of supplies chgs in 4 largest rev ctrs.
- Match to cost report to get supplies CCRs.
- Regress hospital supplies CCR on supplies mix variables plus control variable (CCR for ancillaries excl. supplies).
- Find large, stable, robust impact of charge mix on CCR.
- Best specification combines inpatient and outpatient charges (coincidentally matches data in cost reports).

Regression Results

Supplies CCR as Function of % of Supplies Charges by Sub-Category				
Variable	Coeff	Std Error	T-value	P-value
Intercept	0.108	0.027	3.91	<.0001
CCR, ancill. excl supplies	0.717	0.031	23.07	<.0001
pct_0270 (general supplies)	-0.049	0.027	-1.81	0.07
pct_0278 (implantables)	0.133	0.029	4.56	<.0001
pct_0272 (sterile supplies)	-0.025	0.032	-0.78	0.44
pct_0275 (pacemaker)	0.160	0.040	4.02	<.0001

Source: Analysis of 5% SAF 2004 inpatient and outpatient files matched to 2003 hospital cost reports.

Notes: Dependent variable mean is 0.33. Adjusted R-squared = 0.19. Number of observations is roughly 3,000. Regressions were weighted by supplies charges.

Average CCRs After Budget-Neutrality Adjustment

Estimated CCRs for Supplies Sub-Categories	
Supplies subcategory	Net average CCR after budget-neutrality adjustment
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29
Source: Analysis of 2004 5% standard analytic file and hospital cost report data	

Highlights of Major Gains From Decompression

HSRVcc Weights

DRGs with 10K+ discharges, Ten Largest Weight Increases from Decompression									
				HSRVcc, incorrect (CMS) cost share			HSRVcc, correct cost share		
DRG	Short title	PPS Disch. 2005	2006 wgt	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
515	Defibrillator	57,279	5.52	4.15	4.69	13%	4.90	5.69	16%
552	Pacemaker	80,797	2.10	1.77	1.94	10%	1.97	2.23	13%
551	Pacemaker	53,077	3.10	2.63	2.82	7%	2.87	3.15	10%
498	Spinal fusion	21,188	2.78	2.53	2.64	4%	2.81	3.01	7%
497	Spinal fusion	30,517	3.62	3.33	3.48	5%	3.66	3.90	7%
520	Spinal fusion	16,310	1.68	1.47	1.52	3%	1.63	1.72	5%
471	Hip/Knee	15,407	3.14	2.74	2.91	6%	3.11	3.27	5%
491	Shldr/Elbow	22,356	1.68	1.60	1.64	2%	1.74	1.82	4%
545	Hip/Knee	43,873	2.48	2.41	2.48	3%	2.60	2.71	4%
558	PTCA w DES	189,047	2.21	1.43	1.49	4%	1.75	1.84	5%

Highlights of Major Gains From Decompression

Traditional Cost Weights

DRGs with 10K+ discharges, Ten Largest Weight Increases from Decompression								
			Traditional cost weight with HSRV			Traditional cost weight, standardized		
DRG	Short title	PPS Disch. 2005	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
515	Defibrillator	57,279	5.03	5.81	16%	5.17	5.93	15%
552	Pacemaker	80,797	2.01	2.26	13%	2.04	2.29	12%
551	Pacemaker	53,077	2.92	3.20	9%	2.98	3.25	9%
498	Spinal fusion	21,188	2.87	3.08	7%	2.99	3.20	7%
497	Spinal fusion	30,517	3.72	3.97	7%	3.88	4.12	6%
520	Spinal fusion	16,310	1.65	1.74	5%	1.69	1.78	5%
471	Hip/Knee	15,407	3.11	3.28	5%	3.22	3.38	5%
491	Shldr/Elbow	22,356	1.73	1.80	4%	1.75	1.82	4%
545	Hip/Knee	43,873	2.58	2.68	4%	2.62	2.72	4%
558	PTCA w DES	189,047	1.81	1.88	4%	1.85	1.91	4%

Highlights of Major Losses From Decompression

HSRVcc Weights

DRGs with 10K+ discharges, Ten Largest Weight Reductions from Decompression									
				HSRVcc, incorrect (CMS) cost share			HSRVcc, correct cost share		
DRG	Short title	PPS Disch. 2005	2006 wgt	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
547	CABG	32,200	6.20	5.69	5.57	-2%	5.88	5.72	-3%
549	CABG	12,849	5.10	4.88	4.77	-2%	4.98	4.84	-3%
548	CABG	31,647	4.72	4.18	4.06	-3%	4.38	4.24	-3%
216	Musc. Biop.	19,770	1.91	1.72	1.67	-3%	1.78	1.72	-3%
335	Pelv Proc	12,001	1.10	1.07	1.04	-3%	1.12	1.08	-3%
550	CABG	34,049	3.62	3.46	3.35	-3%	3.57	3.44	-3%
518	PTCA no stent	23,425	1.65	1.14	1.10	-3%	1.37	1.32	-3%

Highlights of Major Losses From Decompression

Traditional Cost Weights

DRGs with 10K+ discharges, Ten Largest Weight Reductions from Decompression								
			Traditional cost weight with HSRV			Traditional cost weight, standardized		
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550	CABG	34,049	3.56	3.44	-3%	3.64	3.50	-4%
518	PTCA no stent	23,425	1.42	1.37	-4%	1.45	1.39	-4%

Summary

- Use statistical analysis to estimate average CCRs for supplies sub-categories
  - Hospital-level, predict supplies CCR as function of supplies mix.
  - Relies on hospital coding of charges by revenue center
  - Relies on strong average relationship between supply mix and CCR.
  - Statistical (regression) analysis appears robust
  - Size of adjustment appears reasonable (vis-à-vis IMS data).
- Calculate costs for supplies sub-categories, force budget-neutrality.
  - Sub-category CCR = supplies CCR + sub-cat. factor from regression.
  - Sub-category cost = sub-category charges x sub-category CCR.
  - Make budget-neutral within each hospital (total supplies cost constant).
- Raises weights for device-intensive cardiac, orthopedic DRGs.
- Only works for some major supplies categories.
  - E.g. IOLs are too small as % of supplies charges.
- But could be further refined
  - Cardiac versus orthopedic implantables (split by MDC)
  - Sub-categories of cardiac (stent versus pacemaker/ICD), split by DRG.
  - Screen hospitals for correct coding of charges (as in OPPS).

Policy Recommendations on IPPS

1. Timing of Implementation

- Fully support goal of improving payment accuracy in the DRG system
  - Payments should match costs as closely as possibly
  - Inpatient procedures should be neither overpaid nor underpaid
- But scope of issues with HSRVcc and CS-DRGs too large to be addressed during comment period
  - Inadequate opportunity for review of alternatives that may appear in final rule
- CMS should defer implementation until FY 2008
  - Sufficient time for further analysis and development of broader consensus

2. HSRV and Cost-Based Weights

- Replace HSRVcc with traditional cost-based weights (OPD-style) and no HSRV
  - 10 national cost-center approach exacerbates charge compression (methodological flaws worsen problem)
  - HSRV questionable policy with cost-based weights
    - Unnecessary change since current standardization policy adjusts for differences due to wage levels, teaching and disproportionate share
      - Fails to consider natural variation in cost that may occur between hospitals
    - Reduces range of variation between low and high DRG weights
    - Disproportionate impact on certain types of hospital and certain types of care (surgical cardiac)
- Traditional cost-based weights alone (OPD-style) most appropriate way to address payment accuracy

3. Improve Accuracy of Underlying Cost Information

- Concurrent with transition to cost-based weights, cost report information and charge compression must be addressed
- Cost Reports
  - CMS convene expert panel to identify methods to better use information from hospital cost reports for appropriate use in the inpatient and outpatient PPS weight-setting processes.
  - Panel must report back with recommendations by March 31, 2007.
- Charge Compression
  - Develop adjustment to ensure implantable devices do not get reduced below cost in weighting systems that rely on converting charges to costs
  - Opportunity to address inpatient and outpatient PPS

4. Severity DRGs

- Develop severity-adjusted DRGs using the existing CMS DRG system
  - CS-DRGs based on APR-DRGs do not reflect changes made to the Medicare DRG system in last two decades
  - Using APR-DRGs as the starting point results in numerous DRG mismatches and abrupt payment shifts unrelated to matching payments to higher severity patients in current DRG system
  - CMS should use the existing Medicare DRGs as the starting point for any severity-related changes.
    - All DRGs or selected ones
    - Consistent with FY 2006 refinements

5. Transition

- Implement cost-based weights and severity DRGs jointly to avoid sharp payment fluctuations from year to year
- Assuming all issues can be addressed, implementation should begin in FY 2008
  - Phase in over 3-4 years
    - Increasing blend of cost and charge weights
  - Adjustments for charge compression to accompany institution of cost-based weights
- Improvements in the use and accuracy of cost reports should be developed and implemented during the transition period

Thank You

Addressing Charge Compression for Implantable Devices

Medtronic, Johnson & Johnson, Boston Scientific,
and St. Jude Medical meeting with MedPAC
May 31, 2006

Agenda

- Introductions
- Recap of May 1 meeting on IPPS
- History of industry concerns with charge compression
- Evidence on existence of charge compression
- Potential approach to counterbalance effects of charge compression
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  - Inaccurate estimates of costs a key barrier to long-term stability in OPPS
    - Payment rates for defibrillators (for example) thousands of dollars off
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  - Significant concern about patient access to therapies shown to represent substantial clinical improvement over current alternatives

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- Numerous analyses over the past 6 years
- Today focus on:
  - Benchmarking charge mark-ups found in OPPS to external data on costs (IMS)
  - Evidence of charge compression from Medicare inpatient and outpatient data

Benchmarking of Charge Mark-Ups Found in OPPS to External Data on Costs

(See attached slides)

Evidence of Charge Compression from Medicare Inpatient and Outpatient Data
&
Potential Approach to Counterbalance Effects of Charge Compression

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- **The issue: one average CCR for all supplies/devices**
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  - Sub-category CCR = actual hospital supplies CCR + national average regression-based sub-category adjustment.
  - "Decompressed" cost = subcategory charges x sub-category CCRs.
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  - Re-estimate DRG weights with "decompressed" cost.

Regression Analysis

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pct_0275 (pacemaker)	0.160	0.040	4.02	<.0001

Source: Analysis of 5% SAF 2004 inpatient and outpatient files matched to 2003 hospital cost reports.

Notes: Dependent variable mean is 0.33. Adjusted R-squared = 0.19. Number of observations is roughly 3,000. Regressions were weighted by supplies charges.

Average CCRs After Budget-Neutrality Adjustment

Estimated CCRs for Supplies Sub-Categories	
Supplies subcategory	Net average CCR after budget-neutrality adjustment
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29
Source: Analysis of 2004 5% standard analytic file and hospital cost report data	

Highlights of Major Gains From Decompression

HSRVcc Weights

DRGs with 10K+ discharges, Ten Largest Weight Increases from Decompression									
				HSRVcc, incorrect (CMS) cost share			HSRVcc, correct cost share		
DRG	Short title	PPS Disch. 2005	2006 wgt	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
515	Defibrillator	57,279	5.52	4.15	4.69	13%	4.90	5.69	16%
552	Pacemaker	80,797	2.10	1.77	1.94	10%	1.97	2.23	13%
551	Pacemaker	53,077	3.10	2.63	2.82	7%	2.87	3.15	10%
498	Spinal fusion	21,188	2.78	2.53	2.64	4%	2.81	3.01	7%
497	Spinal fusion	30,517	3.62	3.33	3.48	5%	3.66	3.90	7%
520	Spinal fusion	16,310	1.68	1.47	1.52	3%	1.63	1.72	5%
471	Hip/Knee	15,407	3.14	2.74	2.91	6%	3.11	3.27	5%
491	Shldr/Elbow	22,356	1.68	1.60	1.64	2%	1.74	1.82	4%
545	Hip/Knee	43,873	2.48	2.41	2.48	3%	2.60	2.71	4%
558	PTCA w DES	189,047	2.21	1.43	1.49	4%	1.75	1.84	5%

Highlights of Major Gains From Decompression

Traditional Cost Weights

DRGs with 10K+ discharges, Ten Largest Weight Increases from Decompression								
			Traditional cost weight with HSRV			Traditional cost weight, standardized		
DRG	Short title	PPS Disch. 2005	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
515	Defibrillator	57,279	5.03	5.81	16%	5.17	5.93	15%
552	Pacemaker	80,797	2.01	2.26	13%	2.04	2.29	12%
551	Pacemaker	53,077	2.92	3.20	9%	2.98	3.25	9%
498	Spinal fusion	21,188	2.87	3.08	7%	2.99	3.20	7%
497	Spinal fusion	30,517	3.72	3.97	7%	3.88	4.12	6%
520	Spinal fusion	16,310	1.65	1.74	5%	1.69	1.78	5%
471	Hip/Knee	15,407	3.11	3.28	5%	3.22	3.38	5%
491	Shldr/Elbow	22,356	1.73	1.80	4%	1.75	1.82	4%
545	Hip/Knee	43,873	2.58	2.68	4%	2.62	2.72	4%
558	PTCA w DES	189,047	1.81	1.88	4%	1.85	1.91	4%

Highlights of Major Losses From Decompression
HSRVcc Weights

DRGs with 10K+ discharges, Ten Largest Weight Reductions from Decompression									
				HSRVcc, incorrect (CMS) cost share			HSRVcc, correct cost share		
DRG	Short title	PPS Disch. 2005	2006 wgt	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
547	CABG	32,200	6.20	5.69	5.57	-2%	5.88	5.72	-3%
549	CABG	12,849	5.10	4.88	4.77	-2%	4.98	4.84	-3%
548	CABG	31,647	4.72	4.18	4.06	-3%	4.38	4.24	-3%
216	Musc. Biop.	19,770	1.91	1.72	1.67	-3%	1.78	1.72	-3%
335	Pelv Proc	12,001	1.10	1.07	1.04	-3%	1.12	1.08	-3%
550	CABG	34,049	3.62	3.46	3.35	-3%	3.57	3.44	-3%
518	PTCA no stent	23,425	1.65	1.14	1.10	-3%	1.37	1.32	-3%

Highlights of Major Losses From Decompression

Traditional Cost Weights

DRGs with 10K+ discharges, Ten Largest Weight Reductions from Decompression								
			Traditional cost weight with HSRV			Traditional cost weight, standardized		
DRG	Short title	PPS Disch. 2005	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
547	CABG	32,200	5.85	5.69	-3%	5.95	5.78	-3%
549	CABG	12,849	4.94	4.81	-3%	5.06	4.91	-3%
548	CABG	31,647	4.40	4.26	-3%	4.48	4.33	-4%
216	Musc. Biop.	19,770	1.77	1.71	-3%	1.83	1.77	-3%
335	Pelv Proc	12,001	1.10	1.07	-3%	1.11	1.08	-3%
550	CABG	34,049	3.56	3.44	-3%	3.64	3.50	-4%
518	PTCA no stent	23,425	1.42	1.37	-4%	1.45	1.39	-4%

Summary

- Use statistical analysis to estimate average CCRs for supplies sub-categories
  - Hospital-level, predict supplies CCR as function of supplies mix.
  - Relies on hospital coding of charges by revenue center
  - Relies on strong average relationship between supply mix and CCR.
  - Statistical (regression) analysis appears robust
  - Size of adjustment appears reasonable (vis-à-vis IMS data).
- Calculate costs for supplies sub-categories, force budget-neutrality.
  - Sub-category CCR = supplies CCR + sub-cat. factor from regression.
  - Sub-category cost = sub-category charges x sub-category CCR.
  - Make budget-neutral within each hospital (total supplies cost constant).
- Raises weights for device-intensive cardiac, orthopedic DRGs.
- Only works for some major supplies categories.
  - E.g. IOLs are too small as % of supplies charges.
- But could be further refined
  - Cardiac versus orthopedic implantables (split by MDC)
  - Sub-categories of cardiac (stent versus pacemaker/ICD), split by DRG.
  - Screen hospitals for correct coding of charges (as in OPPS).

Policy Recommendations on IPPS

1. Timing of Implementation

- Fully support goal of improving payment accuracy in the DRG system
  - Payments should match costs as closely as possibly
  - Inpatient procedures should be neither overpaid nor underpaid
- But scope of issues with HSRVcc and CS-DRGs too large to be addressed during comment period
  - Inadequate opportunity for review of alternatives that may appear in final rule
- CMS should defer implementation until FY 2008
  - Sufficient time for further analysis and development of broader consensus

2. HSRV and Cost-Based Weights

- Replace HSRVcc with traditional cost-based weights (OPD-style) and no HSRV
  - 10 cost-center approach exacerbates charge compression (methodological flaws worsen problem)
  - HSRV questionable policy with cost-based weights
    - Unnecessary change since current standardization policy adjusts for differences due to wage levels, teaching and disproportionate share
      - Fails to consider natural variation in cost that may occur between hospitals
    - Reduces range of variation between low and high DRG weights
    - Disproportionate impact on certain types of hospital and certain types of care (surgical cardiac)
- Traditional cost-based weights alone (OPD-style) most appropriate way to address payment accuracy

3. Improve Accuracy of Underlying Cost Information

- Concurrent with transition to cost-based weights, cost report information and charge compression must be addressed
- Cost Reports
  - CMS convene expert panel to identify methods to better use information from hospital cost reports for appropriate use in the inpatient and outpatient PPS weight-setting processes.
  - Panel must report back with recommendations by March 31, 2007.
- Charge Compression
  - Develop adjustment to ensure implantable devices do not get reduced below cost in weighting systems that rely on converting charges to costs
  - Opportunity to address inpatient and outpatient PPS

4. Severity DRGs

- Develop severity-adjusted DRGs using the existing CMS DRG system
  - CS-DRGs based on APR-DRGs do not reflect changes made to the Medicare DRG system in last two decades
  - Using APR-DRGs as the starting point results in numerous DRG mismatches and abrupt payment shifts unrelated to matching payments to higher severity patients in current DRG system
  - CMS should use the existing Medicare DRGs as the starting point for any severity-related changes.
    - All DRGs or selected ones
    - Consistent with FY 2006 refinements

5. Transition

- Implement cost-based weights and severity DRGs jointly to avoid sharp payment fluctuations from year to year
- Assuming all issues can be addressed, implementation should begin in FY 2008
  - Institute severity DRGs fully in FY 2008
  - Phase in cost-based weights over 4 years
    - Increasing blend of cost and charge weights
  - Adjustments for charge compression to accompany institution of cost-based weights
- Improvements in the use and accuracy of cost reports should be developed and implemented during the transition period

Thank You

/CC

Memorandum

To: IPPS 2007 Proposed Rule analysis clients
From: Christopher Hogan, Direct Research, LLC
Subject: A Proposed Solution for Charge Compression
Date: Revised 6/8/06 to show hospital coding quality.

Executive Summary

This memorandum presents an adjustment for charge compression for supplies and devices. The research does the following:

- Uses regression analysis to estimate the average amount by which cost-to-charge ratios (CCRs) vary across sub-categories of supplies and devices, for example, implantable devices versus general supplies;
- Applies these national average CCR adjustments to individual hospital's supplies CCRs, generating a "synthetic estimate" of CCRs for supplies sub-categories in every hospital. (This is done budget-neutral, keeping total estimated Medicare inpatient supplies cost in each hospital the same before and after adjustment);
- Calculates national average share of supplies charges by sub-category for each DRG, and applies these national charge shares to MedPAR records to produce estimated charges for supplies sub-categories on each MedPAR record. (This step could be skipped if 100% SAF data were used instead of MedPAR);
- Calculates "decompressed" cost by multiplying supplies sub-category CCR by supplies sub-category charges on each claim (along with the other components of costs);
- Generates DRG weights using these "decompressed" costs.

In effect, we take advantage of the detailed coding of supplies charges by revenue center on claims data, to split up the single cost-report CCR into separate CCRs for each supplies sub-category. That split is based on the strong statistical association between mix of supplies charges (by revenue center) in a hospital and the supplies CCR in a hospital. By pooling the information from all hospitals in a regression, we get one set of CCR adjustments reflecting national average CCRs for the sub-categories. We then apply that one national-average set of adjustments to every hospital (combining the adjustments with the hospital's actual supplies CCR), and from there put a "decompressed" estimate of cost on each MedPAR record.

The findings can be summarized as follows:

There is a strong and statistically robust relationship between the mix of charges across supplies sub-categories in a hospital and the hospital's average CCR for supplies. Hospitals with a higher share of charges in the pacemaker and implantable device revenue centers (0275, 0278) have higher supplies CCRs.

The coefficients from this regression provide a data-driven adjustment for creating CCRs for sub-categories of supplies. Only four of the supplies sub-categories have enough charges, on average, to allow such a statistical estimate. On net, after all budget-

neutrality adjustments, the average CCRs for the supplies sub-categories are shown in Table ES-1. The average CCR for all supplies together was 0.33 (top line). But the regression analysis suggests substantial variation in CCR by category. The pacemaker category (which also includes hospital charges for most defibrillators) has an estimated CCR of 0.46 (or just over a 100% average markup). General supplies, by contrast, has an estimated CCR of 0.24 (or just over a 300% average markup).

Table ES-1: Estimated CCRs for Supplies Sub-Categories

Supplies subcategory	Net average CCR after budget-neutrality adjustment
Supplies, Total	0.33
0270 (general supplies)	0.24
0278 (implantables)	0.43
0272 (sterile supplies)	0.27
0275 (pacemaker (and defibrillator))	0.46
all other supplies	0.29

Source: Analysis of 2004 5% standard analytic file and 2003 hospital cost report data

This has a significant impact on some DRG weights. Mainly, cost-based DRG weights would increase for DRGs with substantial charges in the implantable devices and pacemaker/defibrillator revenue centers. These are almost entirely cardiac and orthopedic surgery DRGs. In particular, for defibrillators, the old charge-based weights really may have amounted to "rough justice", in the sense that a properly calculated cost weight (with separate CCRs for device subcategories) would not be that different from a charge-based weight.

A spreadsheet accompanying this memo gives weights for all DRGs.

Here are a few additional comments on the method.

First, this approach seems to meet several tests of the internal validity of the method and external validity of the numbers. The section of the memo regarding the regression gives several statistical "robustness checks" on the numbers. In almost every case, the regression generates the same differential between CCR for implantables and CCR for general supplies. In other words, I would have gotten the same numbers in Table ES-1 from any of several variations on the basic regression. In addition, the "face validity" of the approach is good because the revenue center categories of interest in fact account for a large share of hospital supplies charges. In other words, they are big enough that we *ought* to be able to see their impact on the overall supplies CCR. Finally, although not discussed in the memo, the order-of-magnitude of the resulting CCRs and costs looks roughly correct when compared to the recent Moran et al. study using IMS data on cost of implantables.

Second, some supplies categories are just too small to be used in a regression analysis of this sort. In particular, intraocular lenses account for just 1% of total hospital supply charges (combining inpatient and outpatient). I cannot use this approach to generate a separate CCR for IOLs.

Third, I have done a full "micro-simulation" here, putting detailed costs on each MedPAR record. Much of the complexity of this approach comes from having to put those costs on each and every claim. But, at root, this is a set of national average adjustment factors, applied across-the-board. I expect that a simple national-average adjustment to US charge and cost totals would yield essentially the same answers as are shown here, though I have not demonstrated that. If so, much of the complexity of the method could be avoided -- you could do it in a spreadsheet, once you have the regression results.

Fourth, there is no barrier to refining this further (e.g., separating implantables charges for cardiac and orthopedic by DRG), except the limits of regression analysis. Sub-sub-categories cannot be too small or too correlated with one another. Also, there would appear to be no obvious barrier to doing this for other sub-categories of cost if desired. In other words, again subject to the limits of regression analysis, this could be a tool for CMS to address finer distinctions in CCRs in areas other than supplies.

1 BACKGROUND AND OVERVIEW

For purposes of this analysis, *charge compression* refers to hospitals' practice of taking lower average markups on high-cost devices and supplies, relative to the markup for more routine supplies.

Charge compression is a policy concern because CMS' cost calculations do not account for this. To estimate cost, CMS applies one cost-to-charge ratio (CCR) to all supply/device charges in a hospital. Ultimately, that practice stems from cost reports that pool all supply/device costs within the hospital on a single data reporting line. With charge compression, the use of one pooled CCR for all supplies and devices understates the cost of high-cost devices and overstates the cost of routine supplies.

Fixing charge compression requires that we establish different CCRs for different categories of supplies and devices. The question is how to go about that in a way that CMS might accept, using only CMS administrative data.

Obviously, we cannot estimate each individual hospital's exact CCRs for supply/device sub-categories using CMS administrative data. That hospital-specific information is lost when all supplies/devices costs are mixed together on the cost report.

Instead, we propose a single national-average set of adjustments to hospital CCRs, based on two observations.

- First, revenue center codes on hospital claims provide a detailed breakout of supply/device charges. For example, charges for implantable devices (a category for which charge compression is a concern) are reported separately from general supplies. Further, hospitals by-and-large appear to use these categories correctly. For example, roughly 90 percent of defibrillator discharges have a large charge in either the implantables or pacemaker revenue center.
- Second, there is a strong and stable statistical association between a hospital's mix of supply/device charges by revenue center and the hospital's average CCR for all supplies and devices. All other things equal, the larger the fraction in implantable devices, the higher the CCR, while the larger the fraction in general supplies, the lower the CCR.

So, in broad outline, what we propose to do here is to pool information across hospitals to establish how CCRs vary across sub-categories of devices and supplies, on a national average basis. We pool that information in a regression, looking at the impact that the mix of charges by sub-category has on the overall hospital supplies CCR. The regression coefficients tells us which CCRs for the supplies sub-categories would give us the best fit to the hospital-level data on charge mix and supplies CCR.

We then combine the national average information on how CCRs vary across supplies sub-categories with each hospital's actual supplies CCR. In effect, we show what the hospital's CCRs for the sub-categories would have been, if it matched the national average in terms of higher and lower markups by supplies sub-category.

In generating these supplies sub-category CCRs, I was careful to maintain budget neutrality in each hospital by first "standardizing" each hospital's CCR. That process is described in the methods section. The upshot is that total supply/device costs in each hospital, after my creation of the sub-category CCRs, exactly match total supply/device costs before I made any adjustments.

Following the language used by the U.S. Bureau of the Census, these are "synthetic estimates". We have synthesized the detailed (sub-category) CCR data for each hospital in a way that

- keeps the hospital aggregate data unchanged (total supply/device costs match the existing hospital total), and
- uses national average patterns of CCRs to model the detailed sub-category CCRs within each hospital.

2 METHODS

2.1 Regression specification and sensitivity analysis.

To estimate separate CCRs by revenue center category, I did the following:

- Take the 5% LSD SAF inpatient and outpatient files, CY 2004.
- Pass the inpatient file through the grouper and append the V23 (2006) DRG. (This is required to be able to model the 2007 Proposed Rule rates, and because we will match summary information from this file to 2005 MedPAR).
- Identify all revenue center codes that CMS counts in the supplies and devices revenue center group.
- Aggregate the revenue center codes that individually accounted for less than 5% of supplies charges. (It seemed unlikely that a hospital-level regression would give a stable estimate of impact for rarely-used charge categories.)
- Match to 2003 cost reports with charge-trimmed CCRs:
  - Toss extreme outliers using CMS criteria (<.01, >10) for supplies CCR
  - Toss the top and bottom 2.5% of hospitals, in terms of supplies CCRs, charge-weighted. (That is, drop the hospitals accounting for 2.5% of charges at the top and bottom of the supplies CCR distribution).
- To control for the hospital's overall charging policy, calculate the average CCR for all ancillaries *other than* supplies, based on the cost report data. (An alternative specification used hospital total CCR for all items other than supplies. In either case, we must exclude supplies from the control variable.)
- Run this regression, hospital-level, weighted by supplies charges:
  - Hospital supplies CCR =
    constant +
    hospital CCR for ancillaries excluding supplies +
    percent of supplies by revenue center.
- A larger coefficient on a supplies revenue center shows that supplies in that revenue center are associated with higher average CCR. The model then predicts the differential CCRs across the supplies centers (ie, evaluate the model for a value of 1.0 in one supplies center and 0 in the others.)
- Run several variations, including both inpatient-only and inpatient-plus-outpatient supplies. In theory, because the cost report pools all costs, the inpatient-plus-outpatient model is the preferred specification.

2.1.1 Results

Table 1 profiles 2004 inpatient and outpatient supplies charges for roughly 3,000 short-term general PPS hospitals for which cost report data were available, and for which the supplies CCR on the cost report was kept after trimming. (In other words, the hospitals that will be used to calibrate the DRG weights.) Only four supplies revenue-center categories individually account for at least 5 percent of total supplies charges. These four will be entered separately into the regression. The remainder will be combined into a single "all other" category.

Table 1: Profile of Medicare Hospital Supplies Charges, Calendar Year 2004, 5% Sample Files									
Rev Ctr Code	Short Label	In-patient ($B)	% of inpat	Out-patient ($B)	% of outpat	Total ($B)	% of tot	Memo: Inpat share	Memo: Outpat share
	Supplies Total	$ 2.19	100%	$ 0.45	100%	$2.63	100%	83%	17%
0270	General classification	$ 0.71	32%	$ 0.12	27%	$0.83	31%	85%	15%
0278	Other implants	$ 0.68	31%	$ 0.10	22%	$0.79	30%	87%	13%
0272	Sterile supply	$ 0.44	20%	$ 0.13	29%	$0.57	22%	77%	23%
0275	pace maker	$ 0.21	10%	$ 0.05	12%	$0.27	10%	80%	20%
0271	Nonsterile supply	$ 0.07	3%	$ 0.01	2%	$0.08	3%	90%	10%
0279	Other devices	$ 0.03	1%	$ 0.01	2%	$0.04	1%	82%	18%
0274	Prosthetic/orthotic dev	$ 0.02	1%	$ 0.00	0%	$0.02	1%	94%	6%
0276	Intraocular lens	$ 0.00	0%	$ 0.02	4%	$0.02	1%	1%	99%
0622	Incident to other dxc svc	$ 0.01	0%	$ 0.00	1%	$0.01	1%	76%	24%
0621	Incident to radiology	$ 0.01	0%	$ 0.01	1%	$0.01	1%	51%	49%
0624	Medical investig dev	$ 0.00	0%	$ 0.00	0%	$0.00	0%	97%	3%
0273	take home supplies	$ 0.00	0%	$ 0.00	0%	$0.00	0%	52%	48%
Source: Analysis of 5% sample inpatient and outpatient SAF, for short-term general hospitals with 2003 cost report and non-trimmed CCR (roughly 3,000 hospitals).									
Note: Data totals reflect 5% sample data. If estimated US totals are desired, multiply by 20.									

The table raises an issue with the treatment of intraocular lenses (IOLs). As the rightmost columns of Table 1 show, IOLs are almost exclusively used in outpatient surgery. They account for only about 1 percent of total hospital supplies charges. We believe this is too small a category to allow to estimate a separate CCR for IOLs. They simply do not account for a large enough share of total hospital supplies costs.

A second factor that is worth noting (but cannot be seen on the Table 1 summary) is that the "pacemaker" category actually appears to capture both pacemakers and implantable defibrillators (ICDs). To show this, and to characterize the level of coding accuracy in general, we flagged claims in the 5% sample file that had at least $5,000 or at least $10,000 in charges in implantable devices (revenue center 0278) or in the pacemaker category (revenue center 0275). In other words, for selected DRGs, we wanted to check the extent to which hospitals in fact reported a large charge in the supplies revenue centers of particular interest for this analysis.

Table 2 shows the results for the top 20 DRGs in terms of fraction of cases with significant implantable device charges, using 2004 5 percent sample inpatient SAF data. Coding appears reasonably good but not perfect.

- For defibrillators, roughly 90 percent of defibrillator cases had at least $10,000 in charges in either the pacemaker or implantable device charge category. About half the time, the charge appears in the pacemaker revenue center.
- For spinal fusions of various types, between two-thirds and three-quarters of cases would meet that $10,000 threshold. More complex spinal fusions (e.g., combined anterior/posterior) are more likely to meet that charge threshold.
- For pacemakers, if we switch to a $5,000 threshold, between 80 and 90 percent of cases meet the threshold.
- For hip replacements, a bilateral hip is almost exactly twice as likely to meet the $10,000 threshold as a unilateral hip.
- For stents, less than 40% meet the $10,000 threshold, but about three-quarters meet a $5,000 threshold.

Table 2: Top 20 DRGs by Percent of Cases With Significant Implant Charges

			At least $10K charges in:			At least $5K charges in:		
2006 DRG	Brief Title	Discharges (5% SAF)	Implantable (0278)	Pacemaker (0275)	Either 0275 or 0278	Implantable (0278)	Pacemaker (0275)	Either 0275 or 0278
535	Defib	363	49%	55%	91%	53%	58%	92%
515	Defib	2287	42%	59%	91%	45%	62%	92%
536	Defib	423	49%	52%	89%	55%	54%	90%
496	Spinal fusion	171	83%	0%	83%	86%	0%	86%
546	Spinal fusion	119	73%	0%	73%	78%	0%	78%
552	Pacemaker	4334	6%	67%	72%	11%	83%	89%
551	Pacemaker	2806	11%	62%	71%	17%	77%	87%
471	Hip/Knee bilateral	873	71%	0%	71%	78%	0%	78%
497	Spinal fusion	1416	64%	0%	64%	72%	0%	72%
498	Spinal fusion	1026	62%	0%	62%	71%	0%	71%
118	Pacemaker	372	3%	51%	55%	5%	78%	83%
104	Heart valve	1066	43%	8%	47%	68%	9%	71%
105	Heart valve	1574	42%	6%	44%	66%	7%	68%
545	Hip/knee revision	2219	42%	0%	42%	58%	0%	58%
519	Spinal fusion	647	41%	1%	41%	64%	1%	64%
557	PTCA with stent	5421	38%	0%	38%	75%	0%	75%
525	Heart assist dev	8	38%	0%	38%	38%	0%	38%
111	Major heart proc	544	36%	0%	36%	41%	1%	42%
558	PTCA with stent	8669	36%	0%	36%	74%	0%	74%
544	Hip/knee	21722	35%	0%	35%	63%	0%	64%

Source: Analysis of 2005 5% LDS SAF inpatient file

We calculated the fraction of total supplies charges for the top four revenue center categories, for each hospital. We did this separately for inpatient and outpatient claims.

These charge shares became explanatory variables in the regression below. The omitted category is "all other supplies centers", consisting of everything on Table 1 except the top four categories.

The regression was run with a preferred specification and numerous alternatives. The purpose of the alternatives is to demonstrate that the results are robust to modest variations in the methodology. The specifications are given below.

1) Preferred specification: use total (inpatient and outpatient) charges for calculating charge shares, use all-ancillary CCR excluding supplies as control variable.
2) Exclude most influential top and bottom 1% of hospitals using the DFFITs statistic (explained below).
3) Excluding most influential top and bottom 5% of hospitals using the DFFITS statistics.
4) Use inpatient charges only, for calculating the supply sub-category charge shares.
5) Use total hospital CCR (excluding supplies) instead of CCR for ancillaries excluding supplies.

The DFFITS statistic may require additional explanation. The DFFITS statistic provides a measure of how "influential" a particular datapoint is in determining the slope of the regression line. An influential datapoint is one that strongly affects the slope of the line (due, for example, to being an outlier, or to having an extreme value for one of the predicting variables). By eliminating the most influential datapoints and rerunning the regression, we demonstrate that the regression coefficients are not being driven by a few influential datapoints (e.g., a few large or outlier hospitals), but instead reflect the average relationship of the bulk of the datapoints in the analysis.

The coefficients on mix of supplies charges show a remarkable stability across the regression specifications (Table 3). In each case, the coefficients on implantables and pacemakers are positive and statistically significant, while the coefficients on the other categories are weakly negative.

The final column on the table is the best way to demonstrate the stability of the estimates. The coefficients on the individual categories may vary slightly across specifications. But the differential between the two largest categories -- general supplies and implantables -- hardly changes at all across the specifications. Because we propose to implement a CCR adjustment in a budget-neutral manner, the differential between general and implantable supplies is a good guide to how large the net impact of the CCR adjustment will be. For all except the last specification, the regressions say that we would create a net 18 percentage point differential between the adjusted CCR for implantables (revenue center 0278) and the adjusted CCR for routine supplies. For the pacemaker/defibrillator category (0275), the differential is slightly more variable, ranging from 0.18 to 0.24 across the specifications. The bottom line is that any of the variations shown would generate roughly the same impact on CCRs after budget-neutrality adjustment, because all of them show roughly the same differentials among the categories.

Table 3: Predicting Hospital-Level Supplies CCR Based on Mix of Supplies Charges.					
Variable	Coeff	Std Error	T-value	P-value	Implantable less General Supply Coeff
1: Preferred Specification, Use Inpatient Plus Outpatient Supplies Charges					
Adj R-Sq 0.1928					
Intercept	0.108	0.027	3.91	<.0001	
CCR, ancill. Excl supplies	0.717	0.031	23.07	<.0001	
pct_0270 (general supplies)	-0.049	0.027	-1.81	0.0711	
pct_0278 (implantables)	0.133	0.029	4.56	<.0001	0.18
pct_0272 (sterile supplies)	-0.025	0.032	-0.78	0.4376	
pct_0275 (pacemaker)	0.160	0.040	4.02	<.0001	0.21
2: Same as 1, but toss out top and bottom 1% of influential datapoints					
Adj R-Sq 0.2039					
Intercept	0.103	0.027	3.88	0.0001	
CCR, ancill. Excl supplies	0.717	0.030	23.62	<.0001	
pct_0270 (general supplies)	-0.040	0.026	-1.52	0.1285	
pct_0278 (implantables)	0.138	0.028	4.90	<.0001	0.18
pct_0272 (sterile supplies)	-0.039	0.031	-1.26	0.2075	
pct_0275 (pacemaker)	0.178	0.039	4.60	<.0001	0.22
3: Same as 1, but toss out top and bottom 5% of influential datapoints					
Adj R-Sq 0.2269					
Intercept	0.100	0.026	3.88	0.0001	
CCR, ancill. Excl supplies	0.709	0.028	25.20	<.0001	
pct_0270 (general supplies)	-0.037	0.025	-1.48	0.1396	
pct_0278 (implantables)	0.142	0.027	5.33	<.0001	0.18
pct_0272 (sterile supplies)	-0.024	0.030	-0.82	0.4128	
pct_0275 (pacemaker)	0.143	0.037	3.86	0.0001	0.18
4: Use Inpatient Charges Only					
Adj R-Sq 0.1924					
Intercept	0.110	0.026	4.16	<.0001	
CCR, ancill. Excl supplies	0.715	0.031	23.01	<.0001	
pct_0270 (general supplies)	-0.049	0.026	-1.92	0.0547	
pct_0278 (implantables)	0.128	0.028	4.66	<.0001	0.18
pct_0272 (sterile supplies)	-0.020	0.031	-0.63	0.5271	
pct_0275 (pacemaker)	0.132	0.040	3.32	0.0009	0.18
5: Same as 1, but use total hospital CCR excluding supplies as control variable					
Adj R-Sq 0.2079					
Intercept	0.123	0.027	4.61	<.0001	
CCR, total excl supplies	0.611	0.025	24.48	<.0001	
pct_0270 (general supplies)	-0.098	0.026	-3.70	0.0002	
pct_0278 (implantables)	0.105	0.029	3.64	0.0003	0.20
pct_0272 (sterile supplies)	-0.085	0.031	-2.71	0.0068	
pct_0275 (pacemaker)	0.141	0.039	3.58	0.0004	0.24
Source: Analysis of 5% SAF 2004 inpatient and outpatient files matched to 2003 hospital cost reports.					
Notes: Dependent variable mean is 0.33 for all regressions. Number of observations is roughly 3,000 for all regressions. Regressions were weighted by supplies charges.					

2.2 Practical details of implementation and a choice of methodology.

The previous section provided evidence that the CCRs for implantables and pacemakers/defibrillators are substantially higher than the CCRs for other supplies. This section describes describes what we believe is the preferred method for implementing the adjustment, then briefly describes alternative approaches that might have been used.

2.2.2 Description of preferred methodology

To implement the adjustment, we chose to split up the supplies data on each record into five sub-categories (top four revenue centers plus all other). We did this using a U.S. Census-style "synthetic estimate" approach. That is, we will start with the actual hospital data on hospital charges and CCRs for supplies. Then, beneath the total supplies figure, we generate "synthetic" estimates of the five separate charge sub-categories we wish to estimate. That split is done by imposing the national average charge shares by DRG (from the SAF) to estimate charges in the sub-categories, and imposing the estimated national differentials in CCRs (from the regression above) to estimated CCRs in the sub-categories. (Note that the only reason we use the SAF charge shares here is that we wanted to work from MedPAR, where supplies charges are rolled up to a single total. If we had 100% SAF file data, we could simply have read the exact charges shares from every claim, rather than impute them based on national average supplies sub-category charge shares by DRG.). A separate budget-neutrality (standardization) step ensures that this will leave each hospital's total supplies charges and costs (across all DRGs) unchanged.

These "synthetic" estimates for the five categories can then be used in place of the single supplies charge and cost on the original record. We can then proceed with any of the DRG weight approaches, treating those five new supplies sub-categories however we would have treated the original supplies category.

Before proceeding, it is worth saying that this is probably the most complex and precise method that could be undertaken. It is possible (even likely) that an approximate aggregate adjustment to the data would yield the nearly the same results with far less effort. But the main advantage of this approach is that, once we have done it, we can apply any of the DRG weight calibration methods to the resulting "decompressed" claims data.

The method works as follows.

- **Split the MedPAR supplies charges on each claim into the five sub-categories.** Use 2004 inpatient SAF 5% data to calculate, for each DRG, the percent of supplies charges in each of the five sub-categories. (Recall that the 2006 DRG had previously been appended to this file.) Merge this to MedPAR by DRG, multiply the actual MedPAR supplies total on each line by the DRG sub-category charge shares. This is

our is our synthetic estimate of supplies sub-category charges for each MedPAR record. If we had had 100% SAF data, we would either have skipped this step, or would have calculated the charge shares in greater detail (by DRG *and hospital*) before applying them to MedPAR.[1]

- **Use the coefficients from the preferred regression specification as additive factors for adjusting each hospital's supplies CCR.** Before any standardization or budget-neutrality adjustment, we would assume that the hospital's CCR for general supplies would be .049 below the CCR for the "all other supplies" category (the omitted category in the regression), and that the CCR for implantables would be .133 percent higher, and so on (Table 3, preferred regression specification).
  - **First, we must "standardize" the actual hospital supply CCR to account for the existing mix of supplies used in that hospital.** For example, a hospital with a high share of implantable devices would have a high CCR. We need to remove the effect of the charge mix first, then apply the regression coefficients to that "standardized" supplies CCR. To do this, we sum the estimated supplies charges by sub-category by hospital using MedPAR with the supplies sub-category charges appended. This tells us what fraction of total supplies charges is in each category in each hospital. Multiply by the regression-based adjustment factors to find how much we expect that charge mix to have raised or lowered the hospital's supplies CCR. Then subtract that amount from the hospital's actual supplies CCR. The resulting standardized CCR is the CCR we would expect at each hospital, if each hospital had had exactly the same case mix. ***This net effect of this is to impose budget-neutrality separately on each hospital. Total supplies costs, after decompression adjustment, equal total supplies costs prior to adjustment, separately for each hospital.*** That's because before we apply the adjustment, we have backed out the average impact of that adjustment in this standardization step.[2]
  - **Then, the hospital CCR for each of the five supplies categories is the standardized CCR for all supplies, plus the five additive factors from the regression.** So, for example, the CCR for general supplies is the standardized hospital supply CCR less .049. The CCR for implantables is the standardized hospital supply CCR plus .133. And so on. The CCR for the "all other" supplies category is the standardized hospital CCR (plus zero).

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[1] If 100% SAF data were used this step would not be necessary. Alternatively, if 100% SAF data were available but CMS wished to use MedPAR for the rate setting, we could have calculated the SAF-based charge shares by DRG *and hospital*, and therefore captured each hospital's unique charge shares instead of imposing a national average. CMS has stated that it does not want to use the SAF directly for setting the hospital rates each year. Under this approach, the general pattern of charges from a recent SAF would be imposed on the MedPAR. This avoids having to use current-year SAF data as part of the ratesetting process, at the cost of either imposing national average charge shares by DRG (as is done here), or by imposing the hospital's average charge shares by DRG on all records for that hospital and DRG. In either case, the SAF summary would be a separate step, and the results of that summary would be merged to MedPAR in order to get estimated charges in the supplies sub-categories.

[2] The standardization adjustments were small, on average. On a charge-weighted basis, 1st and 99th percentiles of the standardization adjustments were -0.053 and 0.048, and the range from 25th to 75th percentile was -.007 to -.019. These should be compared to an average supplies CCR of 0.33.

- Multiply charges by CCR to get estimated cost for each of the five supplies sub-catgories, on each claim.
- **Check budget-neutrality for supplies costs.** That is, total US supplies costs using a single CCR for supplies in each hospital must equal total supplies using the synthetic estimate of the five separate supplies categories. In fact, total supplies cost pre- and post-decompression were equal, as they should be by construction.
- **Add the budget-neutral supplies sub-category CCRs to the cost report file.** Read the final, budget-neutral supplies sub-category CCRs off the claims file, by hospital, and add them to the cost report file.

The end result is an enhanced MedPAR file with "synthetic estimates" of charges and costs in the five supplies sub-categories, and an enhanced cost report file with five estimated CCRs for supplies categories instead of one such CCR. The synthetic estimates impose national average charge shares by DRG on each MedPAR record, and impose the national average CCR differentials across the five supplies sub-categories onto all hospitals. (Again, if 100% SAF data were available, we would have either used the actual charge shares or have imposed average charge shares by DRG and hospital rather than by DRG.) The actual hospital data reflect a combination of its own actual supplies charges and CCR and these splits imposed using national average data.

2.2.1 Brief discussion of preferred methodology and alternatives.

This is presented as a plausible way to implement these changes, but is certainly not the only way it could be done. For example, if the entire analysis were done from the SAF instead of MedPAR, we could use actual charge shares throughout and would not need to impose national average charge shares by DRG onto the MedPAR data. This section focuses on the current approach and discusses things that might have been done differently. The end of the paper suggests enhancements or outright alternatives to this approach.

First, with an additive factor used to create the sub-category CCRs, there is the potential for the sub-category CCRs to turn out negative. Sooner or later, that's bound to happen. I checked that, and in this analysis 0.05% (decimal 0.0005) of supplies charges were negative. Obviously this could be fixed by imposing some nominal floor on the CCR (e.g., 0.01) and would have no tangible impact on the results.

Second, the entire process was set up to be additive: the regression gives additive factors for adjusting the CCRs, these are in fact added to the hospital's supplies CCR to generate the sub-category CCRs, and the standardization (budget-neutrality adjustment) was done by subtracting out the hospital-average effects of the CCR adjustments from the hospital's supplies CCR. This approach is internally consistent, and in addition simplifies the standardization by allowing you to ignore the mean value of the other (additive) factors in the regression.[3] This seemed by far the simplest approach.

[3] On a national average basis, the CCR adjustments average to 0.034. That is, by themselves, straight from the regression, they are not budget-neutral. That's because the other factors in the regression (the constant times its coefficient and the control variable times its coefficient) do not average to zero. But there was no

In theory, it should be possible to set up a multiplicative model instead, one in which the predicted CCR for the sub-categories is based on the ratios to the hospitals average supplies CCR (instead of factors added to the hospital's supplies CCR).

A typical approach to generating a multiplicative model is to run a log-log or log-linear model (predict the log of the supplies CCR rather than the CCR itself), then transform the resulting regression estimates into a multiplicative formula at the end by taking anti-logs. (If log(CCR) = A + B, thenCCR = antilog(A)*antilog(B)). A log-log model is not feasible because the supplies sub-category charge shares could be zero. Even a log-linear model (predict log of supplies CCR based on charge shares) may be questionable, as CCRs can be very small and the log transformation is highly nonlinear close to zero.

I ran one log-linear model just to investigate the potential for a multiplicative approach to this adjustment. I regressed log of supplies CCR on the control variable (ancillary CCR excluding supplies) and supplies charge shares, as above, weighting by supplies charges. I then transformed the results into a multiplicative formula and calculated the predicted sub-category CCRs (at the national average value of the control variable). The results where quite close to the additive model: the raw CCR for implantables was 0.19 higher than the raw CCR for general supplies, and the raw CCR for pacemaker/defibrillator was 0.21 higher. These are virtually identical to the differentials show in Table 3, right hand column (the additive model). I therefore concluded that a multiplicative model would give roughly the same results as an additive model.

Fourth, I have made this budget-neutral for inpatient supplies charges, as the proposal here is to apply it to inpatient claims. If this adjustment were applied simultaneously in the IPPS and OPPS settings, you could either make it budget-neutral separately within each system, or make total inpatient and OPD supplies costs budget-neutral. Clearly, there would be operational advantages to keeping the IPPS and OPPS adjustments separate, at the cost of having slightly different net budget-neutral supplies sub-category CCRs applied in the two systems. You can see from Table 1 above that the mix of supplies is modestly different in inpatient and outpatient settings. Thus, a budget-neutrality adjustment in the OPPS setting would probably lead to slightly different net CCRs for the sub-categories than was obtained in the inpatient setting.

2.3 Apply This Adjustment to DRG Weights Calculated Four Ways.

After having put the detailed cost data on every claim, I need to outline how the "decompressed" costs were used in the CMS HSRVcc method. For other approaches to cost-based weights, the modification is obvious -- use the decompressed supplies cost, not the original (compressed) supplies cost.

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need to force this to be budget-neutral at the national level first, before forcing budget-neutrality in each hospital. That additive factor of 0.034 simply got tacked onto each hospital's standardization factor. So, one can simply ignore the other factors in the additive model. If a multiplicative model had been used, it probably would have been necessary to pay more attention to the net impact of the other factors in the model.

To make HSRVcc work with this approach, I did the following:

- Rewrote the HSRV computer program to include the five supplies sub-categories instead of the one aggregate supplies category. So, HSRV would generate 14 charge-based weight for each DRG, one for each of the (now) 14 charge categories.
- Took the final, budget-neutral CCRs for these five categories in each hospital, trimmed them and took the hospital-weighted geometric mean CCRs. (This was in fact the purpose of drawing those CCRs off the claims file and putting them back onto the cost report file.)
- Multiplied these CMS-style (unweighted) CCRs by charges in the five supplies sub-categories to get the (unweighted) cost shares in those categories.
- Forced the total of those five cost shares to match the published CMS cost share for supplies in the aggregate. (So, on net, total estimated supplies cost share, adding the five sub-categories, was forced to match the published CMS value.)
- Weighted the (now) 14 charge-category DRG weights by the CMS-like cost shares to arrive at the final HSRVcc DRG weight.
- For the HSRVcc with corrected CCRs, I performed the same steps, but calculated correctly (charge-weighted) trimmed and weighted CCRs.

For the OPPS-style cost weights, I simply added up the costs on each claim (using the five supplies sub-categories instead of the aggregate supplies category), then proceeded with either traditional standardization or HSRV standardization.

The resulting weights are include in a spreadsheet accompanying this memo. The table below gives the gist of the results: Decompressing costs gives higher DRG weights for procedures using high-cost implantable devices.

Table 4: DRGs With 10K+ Discharges, Ten Largest Weight Increases from Decompression

				HSRVcc, incorrect (CMS) cost share			HSRVcc, correct cost share		
DRG	Short title	PPS Disch. 2005	2006 wgt	As Is	De-com-pres-sed	Gain or Loss	As Is	De-com-pres-sed	Gain or Loss
515	Defibrillator	57,279	5.52	4.15	4.69	13%	4.90	5.69	16%
552	Pacemaker	80,797	2.10	1.77	1.94	10%	1.97	2.23	13%
551	Pacemaker	53,077	3.10	2.63	2.82	7%	2.87	3.15	10%
498	Spinal fusion	21,188	2.78	2.53	2.64	4%	2.81	3.01	7%
497	Spinal fusion	30,517	3.62	3.33	3.48	5%	3.66	3.90	7%
520	Spinal fusion	16,310	1.68	1.47	1.52	3%	1.63	1.72	5%
471	Hip/Knee	15,407	3.14	2.74	2.91	6%	3.11	3.27	5%
491	Shldr/Elbow	22,356	1.68	1.60	1.64	2%	1.74	1.82	4%
545	Hip/Knee	43,873	2.48	2.41	2.48	3%	2.60	2.71	4%
558	PTCA w DES	189,047	2.21	1.43	1.49	4%	1.75	1.84	5%

3 POSSIBLE ADDITIONAL RESEARCH TOPICS.

This section briefly describes additional possible topics for research in this area.

3.1 Further refinements by MDC and revenue center.

There is no technical barrier to separating out charges by revenue center and DRG or MDC. So, for example, subject to the limits of regression analysis, we could try to estimate separate CCRs for cardiac versus orthopedic implantables, or for subsets of cardiac implantables.

In addition, the same technique might be applicable to other revenue centers, but that would depend strongly on the facts in each case. The clear limitations are those of regression analysis: the revenue centers would have to account for a reasonably large fraction of charges in the relevant category, and there could not be too much correlation among the shares of charges in the sub-categories.

3.2 Non-linear regression specification and modeling.

The current approach assumes a simple additive factor to the CCRs. (A fixed number of percentage points, if you will.) That was simple to do, and perhaps a reasonable choice, but it might not be the most natural model for how CCRs would be expected to vary. As described above, I estimated one non-linear model (log CCR as a function of supplies charge mix), and found much the same basic results as I did with the additive model. Nevertheless, for completeness, it might be reasonable to run the complete analysis all the way to DRG weights, using a multiplicative model.

3.3 Correct coding edits .

Table 2 demonstrated that hospital inpatient coding appeared reasonable but not perfect. For example, about 90 percent of defibrillator discharges had a large charge in either the pacemaker or implantable revenue centers. The question that might be addressed here is what (if anything) you would want to do about the other 10 percent of cases?

In the OPPS, a "correct coding" screen was applied to single-procedure claims prior to estimation of the APC weights, for the device-intensive APCs. Claims not passing the screen were not used to set the APC weight. More recently, CMS began requiring hospitals to report the device C-code on such claims to ensure that the charges were being properly captured.

While the concept is simple, the implementation in the inpatient setting might not be. First, the detailed charge data is only available on the SAF. A "correct coding" screen that required charges in the implantables revenue centers could not be directly applied to MedPAR.

Second, some DRGs involve a mix of cases with different levels of implantable device costs. For example, I believe that the "total hip replacement" DRG includes hips, knees, ankles and some other major joint procedures. There would not necessarily be any one "right" level of implantables charges to expect for those DRGs. Other DRGs, such as defibrillator and pacemaker implant, would appear to be more homogeneous. It would not seem unreasonable to screen out claims with trivial (e.g., less than $100) charges in the implantable or defibrillator category before calculating DRG weights.

One further possibility arises if the missing charges for the implantable devices are typically coded as general or routine supplies (that is, are captured in the MedPAR supplies charge category). If hospitals typically report the charges as supplies (and do not, for example, bundle them in with the operating room costs), then the correct-coding screen could be applied without eliminating any MedPAR claims records. It would work in two phases. First, a correct-coding screen would be applied to the SAF, to calculate the share of supplies charges by supplies sub-category for each DRG (or at the hospital by DRG level, using national average data to gap-fill the shares for those hospitals with no or few correctly coded claims). Then, these "correctly coded" charge shares would be applied to MedPAR to get the estimated charges by revenue center category. As long as the charge category on MedPAR captures the charge for the device, this approach would correctly allocate the charges to the implantables revenue centers. (If, by contrast, hospitals just bundle the implantables charge somewhere else, then this wouldn't work.)

3.4 Should this adjustment be budget-neutral?

Cost reports pool all costs for all sites and all payers. In particular, supplies costs reflect both Medicare and non-Medicare cases. If implantable devices account for a larger share of Medicare case-mix than they do of non-Medicare case mix, then in fact this adjustment should not be budget-neutral in total supplies costs. (Obviously, CMS will ensure that the entire weight estimation process is budget-neutral -- the issue here is supplies' share of total estimated costs). If the Medicare case mix is more highly weighted toward implantables, then the aggregate CCR on the cost report currently understates total Medicare supplies cost (because it reflect average supplies mix, not Medicare supplies mix).

This could be checked by using the HCUP all-payer discharge database, combining with the Medicare supplies sub-category charge shares by DRG, and determining whether or not the non-Medicare supplies mix has a lower weight on the pacemaker and implantables categories. It seems implausible that this would have anything more than a slight impact on the DRG weights.

3.5 Could this be done as an aggregate (DRG summary level) adjustment?

Finally, I suspect that the level of detail used in this analysis may be overkill. We are applying national charge shares and a national CCR differentials to the data to generate "decompressed" costs on each claim. Could we get nearly the same estimates, with far

less work, by making these corrections after-the-fact, to national aggregate data just prior to calculation of DRG weights?

I have not done a comparison between the full-detail approach used here and a simple aggregate correction. The methods would appear to be pretty straightforward, and would entail following the steps for the full-detail method, but using aggregate data. This would be the following:

- Summarize SAF supplies sub-category charges in total and by DRG.
- Determine a national average "standardization" factor for the supplies CCR. Multiply the regression-based adjustment by the share of charges in each sub-category, add, and then use this in the next step.
- Calculate budget-neutral sub-category CCRs, as the sum of the US supplies average CCR (0.33) plus the standardization factor plus the adjustment factors from the regression.
- Apply these budget-neutral supplies CCRs to the aggregate supplies charges for each DRG.
- Compare the supplies costs gotten this way (the "decompressed" cost, with separate CCRs for the sub-categories) to the supplies cost obtained in the traditional fashion (total supplies charges times overall supplies CCR).
- Use the resulting percent difference to adjust the cost-based DRG weights. For example, if the "decompressed" supplies cost for defibrillators (DRG 515, say) was 50 percent higher than the "compressed" cost, based on these aggregates, then take whatever supplies cost you were going to use for calculating the cost-based weight for that DRG, and increase it by 50 percent

4 CONCLUSION

This research has demonstrated a feasible approach to solving most of the issue of charge compression. Hospitals appear fairly good about using the correct revenue centers for report inpatient charges for expensive implantable devices. This, in turn, leads to a strong correlation between the mix of charges in the hospital and the CCR for supplies. Hospitals reporting a lot of implantable devices have higher CCRs, all other things equal. Regression analysis can be used to quantify this correlation and generate a reasonably stable and robust estimate of the variation in CCRs across those supplies sub-categories. The resulting national average CCRs by supplies sub-category can be used to estimate "decompressed" supplies costs on each claim record, factoring in a higher CCR for implantable devices and lower CCR for routine supplies. The resulting adjustment increases cost-based DRGs weight for device-intensive DRGs, notably defibrillator, pacemaker, spinal fusions, joint replacements, and stent implants.

This is not a complete solution. It is not a complete solution because it is limited by hospital data reporting, by the structure of the revenue center codes, and by the limitations of a regression-based approach. For certain key DRGs (such as ICD and pacemaker), hospitals largely (though not entirely) appear to report charges in the correct revenue centers. Some classes of implantables either cannot be separately identified by revenue center (or combination of revenue center and DRG), or constitute too small a fraction of charges and therefore will not generate stable estimates in a regression analysis. Perhaps some of these limitations can be improved through further research.

Nevertheless, this method addresses the issue of charge compression for several important categories of implantable devices, including defibrillators, pacemakers, joints, and to some degree stents. Further, it relies solely on Medicare administrative data to make the adjustment. On net, the resulting "decompressed" cost should result in more accurate payments than cost weights calculated without an adjustment for charge compression.

"First Class Care Close to Home"

June 7, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P; Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates

Commenting on: General Comments; HSRV weights

Dear Dr. McClellan:

EMH Regional Health Care System is a nationally recognized healthcare provider serving residents of Lorain and western Cuyahoga counties in Ohio. Comprised of three main campuses- EMH Regional Medical Center, The Hospital for Orthopaedic and Specialty Services and EMH Center for Health & Fitness-the system offers a full range of clinical, health and fitness services.

The cornerstone of the EMH Regional Health Care System is the EMH Regional Medical Center located in Elyria, Ohio. A 374-bed facility, EMH Regional Medical Center was founded nearly 100 years ago, and has evolved into a nine-time winner of the Solucient "100 Top Hospital" designation. Additionally, EMH has been recognized as a top employer by "North Coast 99" for five years, and in fact, is one of the largest employers in a region plagued with job losses in the manufacturing, automotive and steel industries.

In 2005, EMH Regional Healthcare System had 434 licensed beds and 336 staffed beds. Emergency Room visits totaled 71,424 and Surgeries totaled 16,488. There were also 9,064 Cardiac procedures and 8,844 Catheter & E-P Lab procedures. Additionally, 989 Joint Replacement cases were handled by the system last year. EMH Regional Medical Center is full service community hospital including two full service Emergency Departments, Obstetric, Psychiatric and Neonatology services. The proposed changes in the DRG weighting will decrease payments to EMH Regional Medical Center by $4,558,000 over 2006 levels or about a 9% reduction in IPPS payments. This cut in reimbursement will severely impact our ability to fulfill our mission and will result in the curtailing of services and loss of jobs.

We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates (CMS-1488-P). <u>While we are supportive of many of the provisions in the proposed rule, we are very concerned about the proposed methodologies resulting in inaccurate payment amounts, particularly for the cardiovascular services we provide our patients.</u>

As such, we urge CMS to allow time for further study of the proposals until further analyses can be performed to understand the full impact to hospitals and patients, but in the meantime continue with the current charge-based system.

We agree that payment rates should accurately reflect the cost of services provided. Inaccurate rates could limit hospitals' capability to provide services, and thus limit patient access to some therapies. The current proposal, if implemented, could have unintended and inappropriate consequences.

- **Questions have been raised about CMS's proposed rate setting methodology.** Some of these issues include:

  - **CMS used old data to calculate the payment rates.** DRG weights under the new rule are based on data that are 3-5 years old. This particularly impacts technology-based DRGs. Medical technologies typically have a short lifecycle, meaning that many of the innovation technologies available today, such as drug eluting stent technology and cardiac resynchronization therapy defibrillation (CRT-D), were not widely in use at the time these data were collected and the proposed payment will not cover our actual cost.

  - **The use of nonstandard data leads to increased inaccuracy.** The current cost reports were designed for different purpose; CMS should put more thought into how to improve and verify the accuracy of this data prior to making it the basis of its new payment system.

  - **Technical mistakes as well as questionable technical assumptions alter the estimated impact on payments.** In one example, CMS excluded approximately one-quarter of large hospitals' routine day charges in calculating cost-to-charge ratios, which almost doubled the cuts in some DRGs and raised the increase in equal amounts in others. Had these data been included, the large shift in payments for some DRGs would be reduced by nearly half. Another example is in how the cost-to-charge ratios were calculated; CMS failed to adjust for volume of care among hospitals, resulting in a small hospital having as much weight as a large-volume hospital.

  - **Charge compression continues to be a major issue, particularly for costly, high-value medical devices.** Charge compression was not addressed in the FY2007 rule, and is in fact, made worse. Instead of individually analyzing the high cost, high value devices to better understand real costs, CMS decided to put everything together in ten national cost centers. The problem is that there are no standards-most devices and supplies are put in a single cost center, and hospitals across the country put them in different categories, so the real costs may never be captured.

  - **The reimbursement for DRGs like 515 where a majority of the payment is to cover the cost of implants is compounded by the effect of the wage index.** Hospitals in CBSA which have a higher wage index receive considerably higher reimbursement compared to lower wage index CBSAs while the actual cost of the devices is relatively the same. This could limit the availability of such services to areas of the country that have the higher wage indexes.

- **The current proposed DRG payment rates are in some cases the same or lower than the purchase price for ICDs and CRT-Ds.** Proposed rates for ICD and CRT-D procedures are sometimes below the device acquisition cost, not allowing hospitals payment for operating procedures, supplies and personnel. For example, DRG 515, where a majority of ICD implants fall, was paid at a base of $27,158 in 2006; for 2007 Medicare is proposing a sharp decrease in payment of 23%, down to $21,286. We are currently paying $21,700 for our AICD's, which is more than our total payment for DRG 515.

- **If this change is implemented, hospitals could find themselves with limited capabilities to offer their patient's leading-edge, high value lifesaving technologies.** Hospital cannot sustain themselves economically when inaccurate payments do not cover the cost of supplies, equipment, staff and medical devices. This could result in hospitals altering normal treatment patterns, restricting technology selection and limiting patient access in order to avoid extraordinary financial losses. As a result, patients may have limited access to this lifesaving technology because hospitals are not receiving payment that recognizes the full cost of the services provided.

- **This proposed system does not have precedence or transparency.** While the rule provides some description of the methodology for the changes, it does not provide adequate information to calculate the overall impact for the individual measures, nor for the complete proposal. Therefore, we urge CMS to wait, at a minimum, until FY2008 to consider making such drastic and sweeping changes until such a time that more thorough and considered analyses can be performed, and a coalition of stakeholders can research the recommendations that will be better accepted by those affected.

- **The 60-day comment period does not allow the stakeholders adequate time to fully evaluate the consequences.** The major changes and the aforementioned errors in methodology require more than the typical 60-day comment period for stakeholders.

- **As such, CMS should continue with the stable, charge-based system that has been in place for 23 years until a better, more accurate alternative can be found.**

We urge CMS to delay the 2007 proposed changes until more careful analyses are performed, and the full impact to hospitals and patients is understood. Although the proposed changes are in many cases directionally correct, the sheer magnitude of the changes, coupled with the many unintended flaws, requires CMS to delay implementation until a thorough and detailed analysis can be performed that results in more accurate payment for all hospitals.

We appreciate CMS's efforts to improve the inpatient payment system, and agree that it is our mutual goal to improve the lives of Medicare beneficiaries. We all must work together with diligence and with dedication to address these complex issues.

Sincerely,

David A. Cook
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Cc:

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Washington, D.C. 20510-3503
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May 27, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
RE: X STOP Interspinous Decompression System
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir/Madam:

I am writing in support of the X Stop Interspinous Decompression System (hereafter, X Stop). The X Stop is a valuable option for my patients with mild to moderate symptoms due to lumbar spinal stenosis who have not found relief with conservative therapy and who are not good candidates for more aggressive surgery. The patients in my practice who have had the X Stop implanted have all shown substantial clinical improvement.

I see 30 patients a month with lumbar spinal stenosis; 90 percent of whom have Medicare as their primary insurer. About 50 percent of these patients require a laminectomy, some with fusion. The remaining 50 percent of patients are not candidates for surgery, often due to pulmonary and cardiac comorbid conditions. These patients must be managed more conservatively. The typical treatment includes epidural steroid injections, physical therapy (two treatments per week), pain medication (anti-inflammatory drugs and narcotics) and referral to a pain management specialist. When this treatment regimen is not successful, I am now able to suggest the use of the X Stop. About 25 percent of my patients fall in this category.

All of my patients who have had the X Stop procedure have found significant relief in their pain scores, typically dropping from an 8-10 to a low of 1-2. Prior to surgery, they had difficulty walking any distance or even standing up straight. Following surgery all find walking distances far easier and show significant improvement in posture. In no cases have I had to explant the device.

I do X Stop surgeries in the hospital inpatient department. Fifty percent of patients require an ASA Grade 2 anesthesia (basic monitoring) while the other fifty percent require a more involved ASA grade 3 anesthesia (includes vascular access for hemodynamic and fluid control with pharmacologic support).

The X Stop procedure is a valuable addition to the treatment alternatives available to patients with this often debilitating condition, giving better long term results than cortisone injections. It is important that Medicare patients have this treatment option available to them. I urge CMS to approve the new technology DRG add-on for this device.

Sincerely,

Douglas Wong, M.D.

196

CARDIAC SOLUTIONS

JOSEPH A. CAPLAN, M.D., F.A.C.C

VISHAL B. PATEL, M.D., F.A.C.C.

MANOJ RAWAL, M.D.

GABOR S. JILLY, M.D., F.A.C.C.

CHRISTOPHER G. MACKEY, D.O.

June 06, 2006

Centers for Medicare and Medicaid Services
Department of Health Human Services
Attn: CMS-1488P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir:

We are a group of five cardiologists in practice now for few years and we practice in an environment, which is essentially in a retired senior community. We are very heavily medicare based environment. We also have a fair amount of medicare HMOs as our insurance providers.

We do understand that CMS is planning a significant cut in reimbursement for cardiac devices. Given the environment in which we practice as well as the increases in office costs, due to fixed overheads as well as inflationary adjustments, we think that it is going to be fairly hard for a lot of us to practice in this environment with planned cuts to come in. As mentioned, we are fairly heavily senior citizen based practice with a fair need of cardiac devices and with the oncoming changes, it is possible that a couple of our cardiologists would be forced to retire. Hence, it is our sincere request that these proposals need to be very seriously looked at and readjusted in our opinion, to actually give us a fair increase according to the inflation that affects the rest of the country.

Thank you very much.

Sincerely yours,

Vishal Patel, M.D., F.A.C.C.

UNREVIEWED UNLESS SIGNED BY PHYSICIAN

VP/STA/ROS/161704_003

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June 8, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P. O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Docket Number – CMS-1488-P

Dear Dr. McClellan:

I appreciate the considerable effort you and your staff members have put into the development and improvement of the inpatient prospective payment system (IPPS) and specifically recognize the need to continually evolve the payment system to reflect the current landscape within the field of medical services.

Our hospital is a 242 bed acute care hospital located in West Monroe, LA. Our Heart and Vascular Institute is a principal asset of this community and region. As a comprehensive cardiac center, we implant medical devices and perform multiple cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

Origins of the Proposal

The proposed changes appear to have their roots in the Medicare Payment Advisory Commission's (MedPAC) 2005 Report to Congress on Medicare payments for a certain subset of "specialty" hospitals. The MedPAC report raised concerns that the specialty hospitals were selecting the most profitable cases in their area and leaving the other acute care hospitals with less profitable services. Rather than addressing this issue of specialty hospitals in independent fashion, MedPAC recommended changing the payments for ALL acute care hospitals to reduce the incentives in the overall inpatient payment system that fueled the growth of specialty hospital facilities.

CMS should certainly weigh the issues and concerns raised in the MedPAC report when considering policy changes. However, the proposed changes to the inpatient payment system are

the equivalent of throwing the baby out with the bath water. Efforts to address issues identified in the MedPAC report should begin and end with the specialty hospital subset and should not occur in conjunction with payment systems at large for all other hospital facilities.

Issues with the proposed IPPS

Setting aside the issues associated with specialty hospitals, I note two major areas of concern with the proposed IPPS. First, the proposal incorporates an estimated "cost-based" system, rather than a charge-based system for determining the payment weights for each patient category in 2007. Second, the proposal endeavors to change the method of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially in 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Proposing both changes in a single regulation, with implementation in 2007, is unprecedented.

Estimated, not Actual, Costs

CMS proposes to base payments on "costs". In many senses, this is a positive move and is consistent with how private insurers handle costs associated with technology. However, the primary difference between CMS's proposed methodology and the private insurers is the timing of cost data. Private insurers are utilizing data in real-time and are paying actual invoice costs for technology used in the care of patients. In CMS's proposal, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat patients, rather it is a rough approximation of costs. To calculate the cost estimates for Fiscal Year 2007 payments, CMS proposes to utilize hospital claims data from Fiscal Year 2005 and hospital cost reports from Fiscal Year 2003. The cost reports provide the actual costs and the actual charges for all patients (non-Medicare and Medicare patients). The use of any data from Fiscal Year 2003 fails to account for current technology costs – namely drug-eluting stents and bi-ventricular pacemakers/defibrillators, mainstays in the cardiac care landscape. As such, the estimates on cost that CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for the care of Medicare patients.

It is widely known that hospitals across the country do not use a uniform approach to mark-up strategies for technology. Higher cost technologies, such as those used in the treatment of cardiac patients, are often marked up a lower rate than lower cost items. This leads to an inappropriate reflection of cost when attempting to apply derived averages. The following table demonstrates this principle and points out that high-cost technology such as defibrillators and drug-eluting stents would be unfairly accounted for in the proposed reimbursement methodology, causing hospitals to lose substantially with these technologies. This example also highlights why cost reports were never intended to be utilized for the sake of developing accurate procedure specific payment rates.

Impact of Assuming Uniform Mark-Up in Estimating Costs

	Acquisition Cost	Actual Hospital Mark-Up	Charges After Mark-Up	CMS Derived Average Mark-Up	CMS Estimated Costs Based on AvgMark-Up	Delta Between CMS to Actual
Dual Chamber ICD	$ 20,000	200%	$ 40,000	267%	$ 14,998	$ 5,002
Bi-Ventricular ICD	$ 28,000	200%	$ 56,000	267%	$ 20,997	$ 7,003
Drug-Eluting Stent	$ 2,500	200%	$ 5,000	267%	$ 1,875	$ 625
Other Supplies	$ 8	400%	$ 32	267%	$ 12	$ (4)

Gross Impact on Cardiac Care

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 12 to 14% severely impacting these services.

These proposed reductions to cardiac services are severe and are not rooted in any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to pursue a better understanding of actual costs to treat cardiac patients, any such efforts must be made with the intention of producing accurate information – the end result may well be an alteration in the existing infrastructure for cardiac services reimbursement. However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be grave and may potentially limit patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). This is clearly not what CMS intends to achieve with this proposal. As such, delaying the implementation of any changes to cardiac services reimbursement until such time as accurate and appropriate information regarding costs to treat and manage patients with cardiovascular diseases can be compiled is the only prudent approach that can be taken.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure we have built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure I would now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area we build up next to meet patient needs. Obviously, as we are forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

Summary

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments. Again, I appreciate the opportunity to provide commentary on the 2007 CMS IPPS proposal. Finally, I support CMS's efforts to ensure that Medicare beneficiaries have continued access to high quality, efficient, and effective cardiovascular services.

Thank you for your consideration.

Sincerely,

Matt Gibson

Matt Gibson
Executive Director
Glenwood Heart and Vascular Institute
Glenwood Regional Medical Center

Cc: Rodney Alexander
Bobby Jindal
Mary L. Landrieu
Charles F. Scott, GRMC CEO
David Vitter

198

Sioux Valley Hospital
USD Medical Center

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June 1, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

Dear Sir:

Sioux Valley USD Medical Center, Sioux Falls, SD is an urban 400+ bed hospital that provides major cardiology services to patients of this community. Review of the proposed regulations affecting DRG relative weights would drastically reduce the overall Medicare payments for the upcoming year by $3.9 million for 1,342 annual MDC 5 cases. In DRGs 515 (ICD Implant w/o Cardiac Cath), DRG 557 (Drug Eluting Stent with Major CV) and DRG 558 (Drug Eluting Stent w/o Major CV), Medicare reimbursement would be cut by $2.1 million for 440 cases or a 29.0% reduction.

At the same time, while it was noted medical DRGs payment increased $1.3 million, the remaining surgical cases decreased $.2 million, resulting in an overall $2.8 million decrease in total payments.

Review of the proposed regulations indicates that there are several areas that would suggest further examination as noted:

The proposed DRG relative weights would be based upon cost data (instead of charges) that are 3-5 years old and on national averages of hospital's relative values in each DRG. These costs are not accurate and do not include the costs associated with newer technologies such as drug eluting stents. Hence, the reduction noted earlier.

In addition, the manner in which costs are derived from charges assumes that higher cost devices like implantable devices are marked up to the same extent as low cost items. It is well known that this is not the case. As such, this practice will cause an under reporting of costs which leads to a lesser relative weight to the respectable DRGs.

The technical errors and data trimming methods used, most notably the exclusion of 25% of hospital routine day charges when computing the cost-to-charge ratios and CMS's failure to adjust for hospital volume (allowing both small and large hospitals the same weight) are inappropriate and should be corrected.

In addition, CMS solicited comments about the severity adjusted DRGs to be implemented in 2008. However, this is inconsistent with MED PAC recommendation that both should be done in the same year. This would help level the change in reduction from one year to the next.

Lastly, these potential changes, even when corrected, should be phased in gradually over several years to soften the blow.

Sincerely,

Jeff Sandene
CFO

199

SALEM HOSPITAL
REGIONAL HEALTH SERVICES

665 Winter St. SE
Post Office Box 14001
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June 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear CMS,

Salem Hospital is a not-for profit 454 bed regional health service providing comprehensive health care services to a regional area of over 375,000 residents in Oregon.

We are submitting comments on the April 14, 2006 release of the proposed CMS fiscal year 2007 inpatient hospital payment system which proposes a major DRG rebasing.

After a review of your proposal, we are concerned that the depth and breath of this proposal are so sweeping that the methods proposed need significant examination before being implemented. Under the current proposal the DRG rebasing will have a significant negative impact on our cardiac services, with an estimated 9% reduction in cardiology overall, including an estimated 28% reduction in interventional cardiology. Such reductions, if allowed to be finalized, will severely impact our ability to provide vital cardiology services to our regional community.

We agree with your direction to reimburse providers fairly and providers who are most cost efficient in delivery of those services. We also fully agree with the ongoing effort to improve the quality of our hospital care. Among our concerns is that the DRG calculations are based on old data, and cannot truly reflect the current pace of medical device innovation. In addition, the proposed system depends upon the reliability of the current hospital cost reports. We believe that the proposal disproportionally reduces payment for care involving advanced technology. Finally, we believe that technical errors may have been made in your analysis by exclusion of large hospitals in the review.

We encourage you to undertake additional review and analysis addressing the above points prior to such a sweeping change that would negatively impact our ability to provide vital cardiology services to our regional area.

Sincerely,

Jon Pelkey
Cardiac Service Line Director

200

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Judy Silverman, MD
Physical Medicine and Rehabilitation
Electrodiagnosis
Pain Management

6/6/2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: X-Stop interspinous process decompression

To Whom It May Concern:

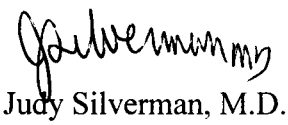
I am a physiatrist, a physician practicing nonsurgical intervention on patients with back and neck pain. I work at St. Mary's Spine Center, where the X-Stop device was developed. This is a minimally invasive surgical procedure that is used to treat people who have spinal stenosis, which presents as leg pain that worsens with walking and tends to resolve with sitting. Spinal stenosis is a condition that affects people as they age. It is most prevalent in Americans who receive healthcare through Medicare benefits.

There are limits to what we are able to do for patients with spinal stenosis in a nonsurgical fashion. We can teach them exercises. We can attempt injections. We can give them medications. The latter two do have potential for side effects and complications. The X-Stop procedure is a minimally invasive surgery that is done under local anesthetic that essentially places lumbar disc segment in a sitting position, which opens up the nerve's holes and allows them improvement in function—specifically, standing and gait, which would translate into increased independence with performing activities of daily living.

Currently, Medicare allows a one-level procedure, but they do not allow a two-level procedure. In obtaining FDA approval for this device, it was tested in patients with both one- and two-level disc disease and was found to be a significant improvement over the traditional treatment. In addition, the previous "standard of care" of surgical intervention included laminectomy, spine decompression surgery, which could have a complication of causing spinal instability. This surgery frequently was then extended to include both the decompression and fusion operation, which required a significant recovery and rehabilitation for patients. The patients who receive an X-Stop are usually better than their presurgical level of function and are able to resume almost all, if not more, activity by one to three weeks after their surgery. A fusion operation recovery can take six months, a year, or sometimes even longer.

I would ask that the Center for Medicare and Medicaid services re-assess and consider approval for hospital payment add-on for an X-Stop, as it is a significant improvement in the traditional surgical intervention for the diagnosis of spinal stenosis.

Sincerely,



Judy Silverman, M.D.

JS/tcg